## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

JOHN HANCOCK LIFE INSURANCE COMPANY, JOHN HANCOCK VARIABLE LIFE INSURANCE COMPANY and MANULIFE INSURANCE COMPANY,

CIVIL ACTION NO. 05-11150-DPW

Plaintiffs,

v.

ABBOTT LABORATORIES,

Defendant.

# ABBOTT'S CORRECTED DEPOSITION COUNTER\_DESIGNATIONS FOR MICHELLE CAMPBELL

Defendant Abbott Laboratories ("Abbott") respectfully submits the attached corrected deposition counter-designations for the February 20, 2007 deposition of Michelle Campbell, Senior Paralegal, Abbott Laboratories.

4498323.1

Respectfully submitted, Dated: February 22, 2008

#### **ABBOTT LABORATORIES**

By: \_\_/s/ Eric J. Lorenzini\_\_\_\_\_ Eric J. Lorenzini

Jeffrey I. Weinberger (pro hac vice) Gregory D. Phillips (pro hac vice) Eric J. Lorenzini (pro hac vice) Ozge Guzelsu (pro hac vice) MUNGER, TOLLES & OLSON LLP 355 South Grand Avenue, Thirty-Fifth Floor Los Angeles, CA 90071-1560 Tele: (213) 683-9100

and

Peter E. Gelhaar (BBO#188310) Michael S. D'Orsi (BBO #566960) DONNELLY, CONROY & **GELHAAR LLP** 1 Beacon St., 33<sup>rd</sup> Floor Boston, Massachusetts 02108 (617) 720-2880 peg@dcglaw.com msd@dcglaw.com

Counsel for Abbott Laboratories

2 4498323.1

### **CERTIFICATE OF SERVICE**

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on February 22, 2008.

Date: February 22, 2008.	
	/s/ Ozge Guzelsu

4498323.1

### Michelle Campbell Deposition Designations

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
02/20/07	Campbell, Michelle	4:15-4:19					
02/20/07	Campbell, Michelle	9:1-9:10	9:11-9:12				
02/20/07	Campbell, Michelle	18:3-18:12					
02/20/07	Campbell, Michelle	21:24-22:2					
02/20/07	Campbell, Michelle	31:17-34:15			2	NO	
02/20/07	Campbell, Michelle	34:18-38:8			1	32	
02/20/07	Campbell, Michelle	39:19-40:8			1 2	32 NO	
02/20/07	Campbell, Michelle	43:13-43:20	43:22-44:8		2	NO	
02/20/07	Campbell, Michelle	45:21-47:3	47:4-47:14				
02/20/07	Campbell, Michelle		47:22-49:5				
02/20/07	Campbell, Michelle		51:14-51:20				
02/20/07	Campbell, Michelle		52:12-53:16				
02/20/07	Campbell, Michelle		54:22-55:18				
02/20/07	Campbell, Michelle	55:19-56:7	56:8-56:15		2	NO	
02/20/07	Campbell, Michelle	56:16-58:7			2	NO	
02/20/07	Campbell, Michelle		59:21-23				

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
02/20/07	Campbell, Michelle		60:9-60:13				
02/20/07	Campbell, Michelle		68:3-69:19				
02/20/07	Campbell, Michelle		72:4-73:23				
02/20/07	Campbell, Michelle	74:8-74:16	74:17-75:20		3	SD	
02/20/07	Campbell, Michelle		76:5-76:11				
02/20/07	Campbell, Michelle	76:12-76:19	76:20-76:21		3	SD	
02/20/07	Campbell, Michelle		77:15-78:5				
02/20/07	Campbell, Michelle		78:14-78:20				
02/20/07	Campbell, Michelle	79:7-79:11			2	NO	
02/20/07	Campbell, Michelle		80:15-80:20				
02/20/07	Campbell, Michelle		81:5-82:7				
02/20/07	Campbell, Michelle	82:16-83:15			2	NO	
02/20/07	Campbell, Michelle		83:24-86:4				
02/20/07	Campbell, Michelle	87:24-90:8	90:9-90:15				
02/20/07	Campbell, Michelle	92:5-93:5	93:6-93:17				
02/20/07	Campbell, Michelle	95:15-96:9	96:10-99:3				
02/20/07	Campbell, Michelle		99:6-101:9				
02/20/07	Campbell, Michelle		103:8-103:23				

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
02/20/07	Campbell, Michelle		104:17- 104:23				
02/20/07	Campbell, Michelle		105:3-105:8				
02/20/07	Campbell, Michelle		105:23- 106:14				
02/20/07	Campbell, Michelle		107:6-107:13				
02/20/07	Campbell, Michelle	107:14- 107:23	108:1- 108:13		2	NO	
02/20/07	Campbell, Michelle		108:19-109:1				
02/20/07	Campbell, Michelle		109:9-109:24				
02/20/07	Campbell, Michelle		111:10- 111:13				
02/20/07	Campbell, Michelle	138:23-139:1	139:2-139:20		7	58	
02/20/07	Campbell, Michelle		141:20-142:2				
02/20/07	Campbell, Michelle	142:22- 143:17			7	58	
02/20/07	Campbell, Michelle	143:19- 143:24			3	SD	
02/20/07	Campbell, Michelle		150:2-151:11				
02/20/07	Campbell, Michelle		153:23- 156:20		10		МВ
02/20/07	Campbell, Michelle	156:21- 157:16			3	SD	
02/20/07	Campbell, Michelle		158:4-159:8		11		МС
02/20/07	Campbell, Michelle	159:9-159:14					
02/20/07	Campbell, Michelle		160:14- 161:23		12		MD

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
02/20/07	Campbell, Michelle		163:13- 164:11				
02/20/07	Campbell, Michelle		167:8-167:11		14		ME
02/20/07	Campbell, Michelle		167:21-168:5		14		ME
02/20/07	Campbell, Michelle		172:11- 173:17				
02/20/07	Campbell, Michelle	175:11-176:2					
02/20/07	Campbell, Michelle	177:5-177:9					
02/20/07	Campbell, Michelle	181:14- 183:13			2	NO	
02/20/07	Campbell, Michelle	186:12- 186:14			17	59	
02/20/07	Campbell, Michelle	187:3-187:10	187:11- 188:13		17	59	
02/20/07	Campbell, Michelle	188:14- 188:22			17	59	
02/20/07	Campbell, Michelle	189:11- 189:13	189:14- 189:24		18	37	
02/20/07	Campbell, Michelle		190:6-190:16				
02/20/07	Campbell, Michelle	191:17- 192:10			18	37	
02/20/07	Campbell, Michelle	193:9-195:19			18	37	
02/20/07	Campbell, Michelle		196:7-197:4				
02/20/07	Campbell, Michelle	200:11- 201:14			2	NO	
02/20/07	Campbell, Michelle	201:17- 201:19	201:20- 202:14		19	NS	
02/20/07	Campbell, Michelle	202:15- 202:22			19	NS	

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
02/20/07	Campbell, Michelle	202:24-203:2	203:3-203:14		20	NT	
02/20/07	Campbell, Michelle	203:20- 204:11			20	NT	
02/20/07	Campbell, Michelle		206:11- 206:14		21		MF
02/20/07	Campbell, Michelle		207:2-207:12				
02/20/07	Campbell, Michelle	207:13- 207:23					
02/20/07	Campbell, Michelle	208:12- 208:19	208:20- 210:16		2	NO	
02/20/07	Campbell, Michelle	212:24-213:6					
02/20/07	Campbell, Michelle	232:18- 234:17	234:18- 234:23				
02/20/07	Campbell, Michelle	238:7-238:11					
02/20/07	Campbell, Michelle	255:21- 255:23			30	OG	
02/20/07	Campbell, Michelle	257:15- 258:10			30	OG	
02/20/07	Campbell, Michelle	268-17- 268:24					
02/20/07	Campbell, Michelle		269:17- 269:23				
02/20/07	Campbell, Michelle	271:5-271:6	271:7-271:16		34	OL	
02/20/07	Campbell, Michelle	271:23-272:2			34	OL	
02/20/07	Campbell, Michelle		272:19-273:8				
02/20/07	Campbell, Michelle	273:9-273:16			34	OL	
02/20/07	Campbell, Michelle	276:23-277:1			36	48	

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
02/20/07	Campbell, Michelle		277:23-278:9				
02/20/07	Campbell, Michelle	278:10- 278:24	279:1-279:8		36	48	
02/20/07	Campbell, Michelle	281:19- 282:15			36	48	
02/20/07	Campbell, Michelle	284:9-284:11			37	49	
02/20/07	Campbell, Michelle	287:14- 288:24			37	49	
02/20/07	Campbell, Michelle	289:1-289:9			37	49	
02/20/07	Campbell, Michelle	290:1-290:16	290:17- 290:19		37	49	
02/20/07	Campbell, Michelle	297:12- 297:23			37	49	
02/20/07	Campbell, Michelle	298:13- 298:22			37	49	
02/20/07	Campbell, Michelle	312:1-312:8			2	NO	

## **Color Key to Deposition Designations**

Designation by Plaintiffs

Counter Designation by Defendants

Designation by Defendants

```
1
          IN THE UNITED STATES DISTRICT COURT
2
          FOR THE DISTRICT OF MASSACHUSETTS
3
4
     JOHN HANCOCK LIFE INSURANCE
     COMPANY, JOHN HANCOCK VARIABLE )
5
6
     LIFE INSURANCE COMPANY, and
7
     MANULIFE INSURANCE COMPANY
                                         )
8
     (f/k/a INVESTORS PARTNER
                                     )
9
     INSURANCE COMPANY),
10
                Plaintiffs, ) Civil Action
11
          VS.
                        ) No. 05-11150-DPW
12
     ABBOTT LABORATORIES,
13
                Defendant. )
14
15
            The videotaped deposition of MICHELLE
16
     CAMPBELL, taken pursuant to the Federal Rules of
17
     Civil Procedure of the United States District Courts
18
     pertaining to the taking of depositions, taken
19
     before LINDA SNODGRASS SABOR, a Notary Public within
20
     and for the County of Cook, State of Illinois, and a
21
     Certified Shorthand Reporter, CSR No. 84-1850, of
22
     said state, at the Westin Chicago North Shore,
23
     601 North Milwaukee Avenue, Wheeling, Illinois, on
24
     the 20th day of February, 2007, at 9:33 a.m.
```

1	PRESENT:
2	CHOATE, HALL & STEWART LLP,
3	(Two International Place,
4	Boston, Massachusetts 02110,
5	Phone 617/248-5000), by:
6	MS. KAREN COLLARI TROAKE,
7	appeared on behalf of the Plaintiffs;
8	
9	MUNGER, TOLLES & OLSON LLP,
10	(355 South Grand Avenue, Suite 3500,
11	Los Angeles, California 90071,
12	Phone 213/683-9276), by:
13	MR. ERIC J. LORENZINI,
14	appeared on behalf of the Defendant.
15	
16	ALSO PRESENT:
17	MR. PETER N. WITTY,
18	Counsel, Abbott Laboratories.
19	
20	
21	VIDEOGRAPHED BY: WES FRANCE, Legal Videographer.
22	
23	REPORTED BY: LINDA SNODGRASS SABOR, RMR, CRR,
24	CSR No. 84-1850.

- 1 MR. WITTY: Pete Witty for Abbott.
- 2 THE VIDEOGRAPHER: Will the court reporter now
- 3 swear in the witness, please.
- 4 (WHEREUPON, the witness was duly
- 5 sworn.)
- 6 MS. COLLARI TROAKE: Eric, we are going to have
- 7 the same stipulations that we've had with all the
- 8 other depositions, correct?
- 9 MR. LORENZINI: Yes.
- 10 MICHELLE CAMPBELL,
- 11 called as a witness herein, having been first duly
- 12 sworn, was examined and testified as follows:
- 13 EXAMINATION
- 14 BY MS. COLLARI TROAKE:
- 15 Q. Okay. Ms. Campbell, could you state your
- 16 name and home address, please.
- 17 A. Michelle Campbell, 1173 Johnson Drive,
- 18 No. 2724, Buffalo Grove, Illinois 600 -- I just
- 19 moved -- 89.
- Q. Thank you.
- 21 Ms. Campbell, I just want to go over a
- 22 few of the ground rules for the deposition so we all
- 23 understand each other.
- 24 If you don't hear a question or you don't

- 1 Q. How long have you worked at Abbott?
- A. A little over five years.
- 3 Q. So did you start in 2002?
- 4 A. I believe it was August of '02, but I'm
- 5 not positive.
- Q. And what's your position at Abbott?
- 7 A. I'm a litigation paralegal.
- 8 Q. And have you had that position the entire
- 9 time you have been working at Abbott?
- 10 A. Yes.
- 11 Q. Do you work full time or part time?
- 12 A. Full time.
- 13 Q. And how many hours a week would
- 14 constitute full time for you?
- 15 A. I don't know. I've never really
- 16 calculated it out. We work whatever we need to.
- 17 Q. Do you get paid any extra if you work
- 18 overtime?
- 19 A. No.
- Q. And have you been full time the entire
- 21 time you've been at Abbott?
- 22 A. Yes.
- 23 Q. How many other litigation paralegals are
- there in the department you're in at Abbott?

- 1 audit -- if that's all right with you.
- A. All right.
- Q. Other than the John Hancock audit, while
- 4 you've been working at Abbott, have you ever worked
- on any other similar types of projects, any other
- 6 audits?
- 7 A. I've never --
- 8 MR. LORENZINI: Objection. Vague.
- 9 But you can answer.
- 10 BY THE WITNESS:
- 11 A. I've never worked on an audit before the
- 12 John Hancock audit.
- 13 BY MS. COLLARI TROAKE:
- 14 Q. In relation to the litigation as opposed
- to the audit, were you asked to look for documents
- 16 that you might have in response to document requests
- 17 in this case?
- 18 A. Are you -- "litigation" meaning both
- 19 cases?
- MR. LORENZINI: Hancock I and II?
- 21 MS. COLLARI TROAKE: No.
- Just Hancock II.
- 23 BY THE WITNESS:
- 24 A. Just Hancock -- I'm sorry.

- 1 in the first case or years ago, so it's nothing
- 2 recent or even in the past year that I can remember.
- 3 Q. Do you recall conducting a search of your
- 4 own files when a request was made of you, whenever
- 5 that was?
- 6 A. I recall looking for my doc -- looking
- 7 for my documents, yes.
- 8 Q. And did you provide your documents to
- 9 someone?
- 10 A. Yes.
- 11 Q. Do you recall who that was?
- 12 A. No, I really don't.
- 13 Q. And when you say your documents, what did
- 14 that include?
- 15 A. I believe we pulled extracts of my
- 16 e-mails, shared drive, hard drive, archived e-mails.
- 17 It may have been more than that, but
- 18 that's what I remember pulling.
- 19 Q. What about paper documents?
- A. I don't remember.
- 21 Generally searching for documents would
- 22 have included everything, so -- but I don't remember
- 23 specifically.
- Q. Do you recall keeping a paper file in

- 1 relation to the John Hancock audit?
- A. No, I don't remember.
- 3 Q. Do you recall having any handwritten
- 4 notes of any kind in relation to the John Hancock
- 5 audit?
- 6 A. I really don't remember. No, I don't
- 7 remember.
- 8 Q. Were you involved at all in reviewing
- 9 your documents prior to giving them to counsel?
- 10 A. I'm not certain. I believe we just
- 11 pulled them, our IT department, and gave them to
- 12 them. I don't -- I don't believe I looked through
- them, but I'm not positive.
- 14 Q. So do you recall whether you were
- involved at all in any redactions that might have
- 16 occurred with respect to the e-mails that were
- 17 provided from your documents?
- 18 A. No, I wouldn't have been involved in
- 19 that.
- 20 Q. You said your supervisor was Ellen Klaus.
- 21 Did she supervise you in relation to your
- 22 work on the John Hancock audit?
- A. We would discuss things, as we would
- 24 discuss all ongoing cases, but she didn't supervise

- 1 MS. COLLARI TROAKE: Did she have a copy.
- 2 BY THE WITNESS:
- 3 A. At one point I had a copy. I don't know
- 4 if I kept it.
- 5 BY MS. COLLARI TROAKE:
- 6 Q. Do you recall -- I'm sorry. Let me start
- 7 again.
- 8 When did you first become aware of the
- 9 audit, the John Hancock audit?
- 10 A. I don't recall the date or the time
- 11 frame.
- 12 MS. COLLARI TROAKE: I actually marked these
- 13 before you guys came in.
- 14 This is actually 2.
- 15 MR. LORENZINI: Okay.
- 16 BY MS. COLLARI TROAKE:
- 17 Q. Okay. Ms. Campbell, I've put in front of
- 18 you what's been marked as Campbell Exhibit 2.
- 19 Do you recognize that document? And feel
- 20 free to -- it's multiple pages, so --
- 21 A. Okay.
- 22 Q. -- feel free to flip through it and let
- 23 me know.
- 24 (WHEREUPON, there was a short

- 1 interruption.)
- 2 BY THE WITNESS:
- 3 A. Okay.
- 4 BY MS. COLLARI TROAKE:
- 5 Q. Do you recognize that document?
- 6 A. I believe I've seen it.
- 7 Q. Okay. When do you recall seeing it?
- 8 MR. LORENZINI: I'm going to object and
- 9 instruct the witness not to answer to the extent it
- 10 discloses documents that were shown during a meeting
- 11 with counsel, but --
- 12 MS. COLLARI TROAKE: Meaning yesterday's
- 13 deposition --
- 14 MR. LORENZINI: Yes. Correct.
- 15 MS. COLLARI TROAKE: That's fine.
- 16 BY MS. COLLARI TROAKE:
- 17 Q. Other than -- you know, exclude, you
- 18 know, what you may have seen yesterday.
- 19 But before yesterday --
- A. Uh-huh.
- 21 Q. -- when do you first recall seeing that
- 22 document?
- A. I don't know if I've seen the document
- 24 before yesterday. I don't remember.

- 1 Q. If you would turn to the page which is
- 2 Bates labeled JHII 11885 -- do you see that?
- 3 It says "Schedule A" at the top.
- 4 A. Yes.
- 5 Q. And Schedule A -- let's see -- is two
- 6 pages.
- 7 A. Uh-huh.
- 8 Q. Do you recall seeing that schedule --
- 9 A. Yes.
- 10 Q. -- before yesterday?
- 11 Okay. When do you first recall seeing
- 12 Schedule A?
- 13 A. I don't know.
- 14 Q. Back to the first page of Exhibit 2, do
- you see the date on the letter is April 12, 2004?
- 16 A. Yes.
- 17 Q. Does that refresh your recollection at
- all as to when you might have seen the letter and
- 19 Schedule A?
- A. I don't know that I've ever seen the
- 21 letter.
- 22 Q. Okay. What about Schedule A? Does that
- 23 refresh your recollection?
- A. I don't remember when I first saw

- 1 Schedule A.
- Q. Ms. Campbell, looking at -- excuse me --
- 3 the first page of Exhibit 2 --
- 4 A. Okay.
- 5 Q. -- you'll see in the first paragraph it
- 6 says, "Pursuant to Section 2.5 of the research
- 7 funding agreement."
- 8 Do you see that?
- 9 A. Yes, I see it.
- 10 Q. Do you recall at any time looking at that
- 11 particular section of the agreement in relation to
- 12 your work on the John Hancock audit?
- 13 MR. LORENZINI: Objection. Vague.
- 14 BY THE WITNESS:
- 15 A. I don't know.
- 16 BY MS. COLLARI TROAKE:
- 17 Q. Excuse me.
- 18 Ms. Campbell, I put in front of you
- what's been marked as Campbell Exhibit 1.
- 20 A. Yes.
- 21 Q. Do you recognize that document?
- A. I have seen it, yes.
- Q. Would you agree with me that it's the
- 24 research funding agreement between Hancock and

- 1 Abbott?
- 2 A. It appears to be. I don't --
- 3 Q. Ms. Campbell, if you could turn to
- 4 Page 10 of the agreement -- the Bates numbers have
- 5 been cut off --
- 6 A. Yeah.
- 7 Q. -- at least on my copy.
- 8 Page 10 of the agreement.
- 9 A. Yes.
- 10 Q. At the bottom of Page 10 there is
- 11 Section 2.5, "Research Reports and Records."
- 12 Do you see that?
- 13 A. I see it, yes.
- 14 Q. Could you just take a moment to read
- 15 Section 2.5, which carries over on to Page 11,
- 16 please.
- 17 (WHEREUPON, there was a short
- 18 interruption.)
- 19 BY THE WITNESS:
- A. Okay.
- 21 BY MS. COLLARI TROAKE:
- Q. Does that refresh your recollection at
- 23 all as to whether you reviewed that section in
- 24 relation to the audit?

- 1 A. No.
- 2 Q. If you could flip back to Page 10,
- 3 please.
- 4 A. Sure.
- Q. And in Section 2.5, about halfway down,
- 6 the sentence beginning "Abbott shall, and shall
- 7 cause each subcontractor -- do you see that?
- 8 A. "Abbott shall --" okay.
- 9 Q. And it says, "Abbott shall, and shall
- 10 cause each subcontractor to, maintain complete and
- 11 accurate records, in sufficient detail and in good
- 12 scientific manner appropriate for patent and
- 13 regulatory purposes and for purposes of
- demonstrating compliance with the terms hereof, that
- 15 fully and properly reflect all work done, results
- achieved and program-related costs expended in
- 17 performance of the research program."
- 18 Do you see that?
- 19 A. Yeah.
- Q. Do you have any understanding as to
- 21 whether Abbott maintained those records?
- 22 MR. LORENZINI: Objection. It calls for a
- 23 legal conclusion. Vague and ambiguous.
- 24 MS. COLLARI TROAKE: Don't make speaking

- 1 objections, Eric.
- 2 BY MS. COLLARI TROAKE:
- Q. You can answer the question.
- 4 A. I don't know. This isn't my area of
- 5 work. I have no way of knowing.
- Q. In relation to the audit, do you recall
- 7 having any understanding as to what those records
- 8 were that this section was discussing?
- 9 MR. LORENZINI: I'm going to object to the
- 10 extent your answer would call for any -- it's based
- on communications with counsel, so exclude that from
- 12 your answer.
- 13 BY THE WITNESS:
- A. Can you state the question again?
- 15 MS. COLLARI TROAKE: Could you read it back for
- 16 me.
- 17 (WHEREUPON, the record was read
- by the reporter as requested.)
- 19 MR. LORENZINI: I'm also going to object that
- 20 it lacks foundation.
- 21 BY THE WITNESS:
- A. I don't recall if I read this, so I don't
- 23 recall if I had an understanding of what documents
- 24 it refers to.

- 1 BY MS. COLLARI TROAKE:
- Q. Do you have any recollection of who might
- 3 have been responsible for maintaining such records
- 4 at Abbott?
- 5 MR. LORENZINI: Objection. Lacks foundation.
- 6 BY THE WITNESS:
- 7 A. I don't think so. I'm really not
- 8 certain.
- 9 BY MS. COLLARI TROAKE:
- 10 Q. A little bit further down in the
- 11 paragraph from where we just read it talks about the
- 12 books and records of Abbott.
- 13 Do you see that --
- 14 A. Uh-huh.
- 15 Q. -- in the next sentence?
- 16 A. Here, yes.
- 17 Q. And a bit further down it says "...shall
- 18 be subject to copying, inspection and audit by (and
- 19 at the expense of) John Hancock at any time and from
- 20 time to time."
- 21 Do you see that?
- 22 A. Yes.
- 23 Q. Do you have any recollection of an
- 24 understanding in relation to your work on the audit

- 1 as to what "copying, inspection and audit by...
- 2 John Hancock" referred to?
- 3 And, again, I would say exclude anything
- 4 from counsel in your answer, just your under --
- 5 recollection of any understanding you had.
- 6 MR. LORENZINI: Independent of communications
- 7 with counsel.
- 8 MS. COLLARI TROAKE: Yes, absolutely.
- 9 MR. LORENZINI: Objection. Lacks foundation.
- 10 The witness testified she --
- 11 MS. COLLARI TROAKE: I'm just asking if she
- 12 recalls, if she had an understanding.
- 13 BY THE WITNESS:
- 14 A. Independent of communications with the
- 15 attorneys.
- 16 BY MS. COLLARI TROAKE:
- 17 Q. Yes.
- 18 A. I don't believe so, no.
- 19 Q. Ms. Campbell, going back to Exhibit 2 and
- 20 looking at the letter again -- and I understand you
- 21 don't recall receiving this letter, but there's a
- 22 list of items, 1 through 7, that carries over to
- 23 Page 2 of the letter --
- 24 A. Okay.

- 1 Q. -- and there are a number of sections of
- the agreement that are referred to, Section 2.2,
- 3 2.3, 4.3, and again 4.3 on the next page.
- 4 Do you recall ever looking at Exhibit 1,
- 5 the agreement, and referencing those particular
- 6 provisions of the agreement in relation to your work
- 7 on the audit?
- 8 A. No, I don't recall ever doing that.
- 9 Q. Do you recall how you obtained a copy of
- 10 Schedule A?
- 11 A. No, not specifically.
- 12 Q. Do you recall who gave it to you?
- A. Most likely the attorneys, but I don't
- 14 recall specifically.
- 15 Q. And would that have been Mr. Wittenberg?
- 16 A. Yes.
- Well, or outside attorneys. I don't
- 18 really remember specifically.
- 19 The Abbott attorney was Ken Wittenberg.
- 20 Q. And if it was an outside attorney, do you
- 21 recall who that would have been at the time?
- 22 A. It could have been Larry Desideri,
- 23 Kathleen Barry, Steve D'Amore.
- 24 Those were the attorneys I recall --

- 1 BY THE WITNESS:
- 2 A. Probably.
- 3 BY MS. COLLARI TROAKE:
- 4 Q. But you don't have a specific
- 5 recollection of having that kind of discussion with
- 6 Mr. Wittenberg?
- 7 A. Not a specific recollection, no.
- 8 Q. But generally you recall having that kind
- 9 of discussion with him at some point?
- 10 A. Generally on any document request or
- 11 discovery matter I would have a discussion with the
- 12 attorneys on people and/or documents.
- Q. Did you ever make a list of individuals
- that needed to be contacted in relation to
- 15 collecting documents that were called for by
- 16 Schedule A in Exhibit 2?
- 17 MR. LORENZINI: Objection. Vague and ambiguous
- with respect to creating a list.
- 19 BY THE WITNESS:
- A. I don't know if I ever made a list.
- 21 BY MS. COLLARI TROAKE:
- Q. Would it be your normal practice in
- responding to a subpoena or a document request when
- you're having to collect documents in a litigation

- 1 matter to make a list of people that you would need
- 2 to contact in relation to collecting documents?
- 3 MR. LORENZINI: Objection. Vague and
- 4 ambiguous.
- 5 BY THE WITNESS:
- 6 A. My general practice -- I might not know
- 7 at the outset who to contact. Usually that would
- 8 come in e-mail communications as we identify people.
- 9 For normal subpoenas, like divorces, we
- 10 know off the top of our heads who to contact.
- 11 BY MS. COLLARI TROAKE:
- 12 Q. Now, when you say -- I'm sorry -- you
- 13 wouldn't know at the beginning, but you might figure
- 14 it out through e-mail communications, who are you
- 15 communicating with by e-mail to figure it out?
- 16 A. Related to this or --
- 17 Q. Generally.
- 18 A. -- in general?
- 19 It depends on the type of case. Abbott
- 20 is a very large company. The attorney may say try
- 21 this person. I may say, well, I know this person
- works in pharmaceuticals, I'll call them. I may
- call ten other people until I get to a person who
- 24 actually has knowledge of the topic.

- 1 Q. Uh-huh.
- 2 A. I don't have knowledge of all of the
- 3 topics in Abbott, so I wouldn't know -- reading
- 4 this, I wouldn't say, oh, yeah, instantly I'll make
- 5 a list, I know I need to contact all these people.
- 6 Q. At some point as you're making contact
- 7 with various individuals and identifying who the
- 8 appropriate people are, would you ordinarily make a
- 9 list or take notes as to who the relevant people are
- that you'd need to collect documents from?
- 11 MR. LORENZINI: Objection. Compound. Vague.
- 12 BY THE WITNESS:
- 13 A. I don't think I have a general practice.
- 14 BY MS. COLLARI TROAKE:
- 15 Q. How do you keep track of who you need to
- talk to and who has given you documents?
- 17 A. Sometimes we keep a log of who's given us
- documents, sometimes I make a note in e-mail,
- 19 sometimes we send notes to the attorney saying
- 20 you'll be getting these and we don't keep logs.
- Q. Do you recall whether with respect to the
- 22 John Hancock audit you kept a log of individuals who
- 23 were -- who were contacted and who were asked to
- 24 provide documents?

- 1 MR. LORENZINI: Objection. Vague and ambiguous
- 2 as to the definition of "log."
- 3 But you can answer.
- 4 BY THE WITNESS:
- 5 A. I don't remember specifically.
- 6 BY MS. COLLARI TROAKE:
- 7 Q. What would a log look like?
- 8 A. Generally --
- 9 THE WITNESS: I'm sorry.
- 10 MR. LORENZINI: Objection.
- 11 BY THE WITNESS:
- 12 A. It could be a Word document, an Excel
- 13 document.
- 14 It looked like a chart, generally.
- 15 BY MS. COLLARI TROAKE:
- 16 Q. And you don't recall whether something
- 17 like that was created with respect to the
- 18 John Hancock audit?
- 19 A. No, I don't remember.
- 20 Q. If one were created, would you have been
- 21 the person responsible for creating it?
- 22 MR. LORENZINI: Objection.
- 23 BY THE WITNESS:
- A. Possibly.

- 1 BY MS. COLLARI TROAKE:
- 2 Q. But you don't recall?
- 3 A. I don't recall if one was created.
- 4 Q. When you were asked to collect documents
- 5 in relation to this litigation, your documents --
- 6 A. Uh-huh.
- 7 Q. -- did you look to see if there was a log
- 8 of that kind?
- 9 MR. LORENZINI: Objection.
- 10 BY THE WITNESS:
- A. I collected anything that had to do with
- the matter. I did not specifically look to see if
- there was a log. If there was one, it would have
- been given to our outside attorneys.
- 15 BY MS. COLLARI TROAKE:
- 16 Q. But you don't recall whether you found
- 17 one and gave it to your attorneys.
- 18 A. I don't recall if there was one. I
- 19 didn't specifically look for one. I recall giving
- 20 them all of my Hancock documents -- files,
- 21 electronic, whatever, files.
- Q. Other than possibly discussing Schedule A
- 23 with Mr. Wittenberg, do you recall discussing
- 24 Schedule A with anyone else at Abbott at any time in

- 1 the course of your work on the audit?
- 2 A. Yes.
- 3 Q. Who?
- 4 A. Ken Stiles, Rich Pinto -- can I clarify
- 5 portions of Schedule A? Maybe -- I don't know if I
- 6 discussed the entire schedule with each person.
- 7 But Ken Stiles, Rich Pinto, Amy Potthoff,
- 8 Chris Sopata, Richard Herst --
- 9 Q. I'm sorry. Chris --
- 10 A. Sopata.
- 11 S-o-p-a-t-a, I believe.
- 12 Q. And I'm sorry. You were saying someone
- 13 else after --
- 14 A. Richard Herst, I believe Rhonda Rickey --
- 15 I'm still thinking -- I believe portions of it or
- all of it would have been discussed with Keith
- 17 Hendricks.
- 18 Q. Anyone else?
- A. Not that I can remember, no.
- Q. Do you recall discussing it with
- 21 Tom Woidat?
- A. I recall discussions with Tom Woidat in
- 23 general, not specifically the schedule.
- Q. You recall discussions about the audit

- 1 generally, but not specifically Schedule A, is that
- 2 what you mean?
- A. I recall discussions about document --
- 4 documents he maintains, which may have been part of
- 5 the audit or the litigation. I don't remember.
- 6 Q. Who is Ken Stiles?
- 7 A. He's in GPRD finance, global
- 8 pharmaceutical research and development.
- 9 I believe he's assistant controller, but
- 10 I'm not positive on that.
- 11 Q. That's his current role?
- 12 A. I believe that's been his role for a
- 13 number of years, but, again, I'm not positive on the
- 14 title.
- 15 Q. Okay. Was he in that same role, do you
- 16 think, back in 2004?
- 17 A. I believe so, but I'm not certain.
- 18 Q. What about Richard Pinto?
- 19 A. He works in GPRD finance. I don't know
- 20 his specific title.
- Q. And, again, you think he was in that role
- or that division back in 2004?
- A. I believe he was in GPRD finance.
- Q. And who is Amy Potthoff?

- 1 recall about your discussions with him regarding
- 2 Schedule A?
- 3 MR. LORENZINI: Objection.
- 4 I'll just instruct the witness to exclude
- 5 from your answer any aspect of that communication
- 6 that involved passing on -- that involves disclosure
- 7 of privileged communication from the attorneys.
- 8 Do you think you -- do you have
- 9 recollection --
- 10 THE WITNESS: No, other --
- 11 MR. LORENZINI: -- independent of that?
- 12 THE WITNESS: No, no.
- 13 BY MS. COLLARI TROAKE:
- 14 Q. Do you have any recollection of
- discussions with Mr. Stiles about what documents
- needed to be collected and what individuals might
- 17 have those documents in relation to Schedule A?
- MR. LORENZINI: You can -- you can answer that.
- 19 BY THE WITNESS:
- 20 A. Yes.
- 21 BY MS. COLLARI TROAKE:
- 22 Q. And what do you recall about those
- 23 discussions?
- MR. LORENZINI: Again, if there is any aspect

- 1 of your answer that would disclose communication
- 2 from counsel about what documents to be produced or
- 3 collected, exclude that, but you can testify as to
- 4 your communications with him generally about what
- 5 documents he had or where documents would be
- 6 located.
- 7 THE WITNESS: Okay.
- 8 BY MS. COLLARI TROAKE:
- 9 Q. I'm not looking for legal advice here.
- 10 I'm looking for the mechanics and the logistics of
- 11 how you went about the audit.
- 12 So what you can recall about what you
- discussed with Mr. Stiles about what he may have,
- what others might have, and what documents they had
- to be collected in relation to Schedule A.
- A. The only thing I recall specifically
- 17 discussing with Mr. Stiles was timesheets.
- 18 Q. And what do you recall about that
- 19 discussion?
- A. He told me that they were in corporate
- 21 records.
- Q. And what does that mean, "in corporate
- 23 records"?
- A. Housed in corporate records. It's a

- department, I guess, for Abbott that houses records.
- 2 Q. Is that the same or different than the
- 3 RIC, Research Information Center?
- A. Different.
- Q. Different.
- 6 And where are the corporate records kept,
- 7 physically kept?
- 8 A. In the corporate records building.
- 9 Q. Which is where?
- 10 A. Somewhere in North Chicago.
- 11 Q. What else can you recall about your
- discussions with Mr. Stiles about timesheets?
- A. I recall that he was going to have
- someone in his department either contact corporate
- records or help me in contacting corporate records
- 16 to locate them.
- 17 Q. Do you recall who that was?
- 18 A. No.
- 19 Q. Do you recall whether you contacted
- 20 someone in corporate records or someone else did?
- 21 A. Regarding timesheets.
- 22 Q. Yes.
- 23 A. No.
- Q. Do you recall anything else that you

- 1 discussed with Mr. Stiles about particular documents
- 2 or individuals?
- 3 A. Can I look at the schedule?
- 4 Q. Yes.
- 5 A. I don't recall specifically. I had a
- 6 number of conversations with Ken throughout the
- 7 first case, the second -- well, maybe not the first
- 8 case -- the second case and the audit. I don't
- 9 remember specifics.
- 10 Q. The only specific you remember is in
- 11 relation to the timesheets?
- 12 A. The only specific conversation I recall
- 13 having with him.
- 14 Q. Do you recall when that was?
- 15 A. I believe it was at or directly after the
- 16 initial meeting arranged by Ken Wittenberg.
- 17 Q. Do you recall when that initial meeting
- 18 was?
- 19 A. Sometime in '04.
- 20 And I only recall that because I saw a
- 21 document. Other than that, I didn't remember.
- Q. Did you eventually get these timesheets
- at some point and collect them?
- A. They were produced.

- 1 Q. What do you mean by "they were produced"?
- A. They were produced in the audit. I don't
- 3 know if I physically got them or if they were
- 4 dropped off or who put them there. They were
- 5 produced in the audit.
- 6 Q. When you say "produced," were the
- 7 originals produced, did you produce copies? What --
- 8 what do you mean by that?
- 9 A. If they were housed in corporate records,
- 10 it would have been the originals.
- 11 Q. Why is that?
- 12 A. Because corporate records allowed us to
- 13 stage the originals for viewing by the auditors.
- 14 Q. What do you mean by "stage the
- 15 originals"?
- A. We set them in a warehouse. To save
- money, rather than copying them, they let us use the
- 18 originals.
- 19 Q. Other than timesheets from corporate
- 20 records, what other originals from corporate records
- 21 did you set up in the warehouse?
- A. Anything pertaining to the compounds that
- 23 corporate records maintained.
- Q. And what did that include?

- 1 A. I don't know.
- 2 I said give me everything you have
- 3 pertaining to the compounds, and they put them in
- 4 corporate records.
- 5 Q. Did you identify for them on Schedule A
- 6 what it was you were looking for?
- 7 A. No.
- 8 Q. And when you say you asked for everything
- 9 in relation to the compounds, do you mean the
- 10 program compounds that were covered by the
- 11 agreement, Exhibit 1?
- 12 A. The program compounds, yes.
- 13 Q. The ones --
- 14 A. The program compounds, yes, in the
- 15 agreement. Yeah.
- 16 Q. When you got everything from them in
- 17 relation to the program compounds, did you review
- 18 those documents prior to putting them in the
- 19 warehouse and prior to the auditors seeing them to
- 20 determine what categories on Schedule A those
- 21 documents related to?
- A. I don't know.
- 23 Q. You don't know whether you reviewed them
- 24 or not.

- 1 A. I don't remember.
- Q. Do you know if anyone else did?
- 3 A. I don't believe so.
- 4 Q. Do you recall keeping track in any way
- 5 how the documents you were collecting in relation to
- 6 the audit matched up with the categories listed on
- 7 Schedule A?
- 8 MR. LORENZINI: Objection. Vague and
- 9 ambiguous.
- 10 Could you repeat the question, please?
- 11 MS. COLLARI TROAKE: Can you read it back.
- 12 (WHEREUPON, the record was read
- by the reporter as requested.)
- 14 BY THE WITNESS:
- 15 A. No, I don't recall.
- 16 BY MS. COLLARI TROAKE:
- 17 Q. For example, you didn't have a copy of
- 18 Schedule A -- when you got documents in from someone
- 19 within Abbott, you didn't look through that box of
- 20 documents, for example, and then look back at
- 21 Schedule A and say, oh, yes, that responds to, for
- 22 example, Paragraph 1-B, and check that off and keep
- 23 track of it in some way?
- 24 MR. LORENZINI: Objection. Vague and

- 1 ambiguous.
- 2 BY THE WITNESS:
- 3 A. I don't believe so.
- 4 BY MS. COLLARI TROAKE:
- 5 Q. Do you know if anyone else at Abbott did
- 6 that task?
- 7 A. I don't know. I don't believe so.
- 8 Q. Anything else you can recall discussing
- 9 with Mr. Stiles about Schedule A that we haven't
- 10 already talked about?
- 11 A. The only thing I specifically recall are
- 12 the timesheets.
- 13 Q. Do you recall any other discussions with
- 14 him about the audit generally, not specifically tied
- 15 to Schedule A?
- 16 A. I believe I had discussions with him, but
- 17 I don't -- I don't remember specifically.
- 18 MR. LORENZINI: Karen, we've been going for a
- 19 little over an hour. Do you want to take a break at
- 20 a convenient time?
- 21 I don't want to interrupt your flow of
- 22 questioning, but whenever --
- MS. COLLARI TROAKE: Yeah, we can do it now, if
- 24 you want to take a five-minute break.

- 1 MR. LORENZINI: Yeah, just a quick break.
- 2 MS. COLLARI TROAKE: That's fine.
- 3 THE VIDEOGRAPHER: We are going off the record
- 4 at 10:40 a.m.
- 5 This concludes Tape No. 1.
- 6 (WHEREUPON, a recess was had.)
- 7 (WHEREUPON, a document was marked
- 8 Campbell Exhibit No. 3, for
- 9 identification, as of 2/20/07.)
- 10 THE VIDEOGRAPHER: We are going back on the
- 11 video record at 10:50 a.m.
- This is the beginning of Tape No. 2.
- 13 BY MS. COLLARI TROAKE:
- 14 Q. Okay. Ms. Campbell, before we took our
- break, you mentioned that you recalled your
- 16 conversation with Mr. Stiles about the timesheets
- was probably around the time of that initial
- 18 meeting.
- 19 Is that right?
- 20 A. Yes.
- Q. And I have put in front of what you has
- been marked as Campbell Exhibit 3, which is two
- 23 pages.
- 24 If you could take a look at that and let

- 1 me know whether that refreshes your recollection
- 2 about when this initial meeting was that you were
- 3 referring to.
- 4 (WHEREUPON, there was a short
- 5 interruption.)
- 6 BY THE WITNESS:
- 7 A. Okay.
- 8 BY MS. COLLARI TROAKE:
- 9 Q. Does that refresh your recollection that
- this initial meeting was around April 20th, 2004?
- 11 A. It doesn't refresh my recollection, but I
- have no reason to doubt that this wasn't the initial
- 13 meeting.
- 14 Q. So you think that your conversations with
- 15 Mr. Stiles about the timesheets were around
- 16 April 20th, 2004?
- 17 A. If not in that meeting, I believe they
- were around that time frame.
- 19 Q. And previously you said you also had
- 20 discussions with Richard Pinto regarding Schedule A,
- 21 which is attached to Exhibit 2.
- 22 A. Yes.
- Q. What do you recall about your discussions
- 24 with Mr. Pinto about Schedule A?

- 1 summary of the meeting after you had the meeting?
- 2 A. Not to me.
- 3 Q. The other person you mentioned about who
- 4 you had discussions about Schedule A with was Chris
- 5 Sopata --
- 6 A. Sorry.
- 7 Q. -- what can you recall about your
- 8 discussions with -- is that a him or a her?
- 9 A. Chris Sopata is a him.
- 10 I recall sending him an e-mail. I
- 11 believe I sent it to Richard Herst at the same time.
- 12 I don't know if it was the same e-mail. And then I
- had a conversation, I believe, with Richard and
- 14 Chris at the same time.
- Q. Was that conversation in person?
- 16 A. No. It was phone.
- 17 Q. And what can you recall about those
- 18 discussions?
- A. I recall telling them that there was
- going to be an audit and I recall going through
- 21 locations where documents pertaining to the
- 22 development of the -- the documents pertaining to
- the therapeutic compounds they supported, where they
- 24 might be located.

- 1 Q. Anything else you can recall?
- 2 A. No.
- 3 Q. Do you recall when that conversation was?
- 4 A. Somewhere around the time of this initial
- 5 meeting, but I don't recall specifically.
- 6 Q. And did they tell you where the documents
- 7 would be in relation to their particular compounds?
- 8 A. They told me potential places that
- 9 documents might be located.
- 10 Q. And what were those places?
- 11 A. I don't remember specifically.
- 12 There was the RIC.
- 13 Q. And the RIC is --
- 14 A. The Research Information Center. Sorry.
- 15 I believe they identified either shared
- drives or perhaps websites, but I don't remember
- 17 specific -- or, portals they might have used. I
- don't remember specifically, but I believe they
- 19 identified those places.
- 20 Q. Did they identify any individuals that
- 21 you should contact?
- 22 A. I don't remember.
- 23 Q. Did you discuss particular categories of
- 24 documents on Schedule A that they would be

- 1 Q. Do you recall what type of documents she
- 2 indicated she might have?
- 3 A. No.
- 4 Q. Anything else you can recall about your
- 5 communications with Ms. Rickey about the audit or
- 6 Schedule A specifically?
- 7 A. I don't recall discussing Schedule A with
- 8 her, no, other than discussions about where her --
- 9 she or her -- her department might have housed
- documents pertaining to whatever compounds they
- 11 supported in -- in the research funding agreement,
- 12 the compounds listed in the research funding
- 13 agreement.
- 14 Q. And did she indicate, as did Mr. Sopata
- and Mr. Herst, that they would be in the Research
- 16 Information Center?
- 17 A. I don't remember.
- 18 Q. You also said you recalled discussions
- 19 with Keith Hendricks about Schedule A.
- What can you recall about those
- 21 discussions?
- A. I recall discussing PEC documents.
- Q. What's PEC?
- 24 A. Pharmaceutical Executive Committee. It

- 1 could have been for the audit or the litigation. I
- don't remember.
- 3 And I recall discussing TEC, Therapeutic
- 4 Executive Committee. It could have been for the
- 5 audit or the litigation.
- 6 And those are the two things I
- 7 specifically remember talking to Keith about.
- 8 Q. Do you recall when those discussions
- 9 occurred?
- 10 A. No, I really don't.
- 11 Q. And what did he tell you about the PEC
- 12 and the TEC?
- A. I believe for the audit he provided or
- 14 told me where to collect PEC summaries or minutes or
- 15 something. I don't know specifically what they're
- 16 called.
- 17 And I don't remember what he told me for
- the audit regarding the TEC -- TECs, to the extent
- 19 they exist.
- Q. What about the PECs?
- A. I believe he told me for the audit where
- the document summaries might be located or he had
- them and where I could collect them from.
- Q. Do you recall where he told you they

- 1 would be located?
- 2 A. No.
- 3 Q. Did he provide you with the names of any
- 4 individuals who you should contact in relation to
- 5 collecting documents with respect to the audit?
- 6 A. With respect to the audit, I don't
- 7 remember.
- 8 Q. Looking back at Exhibit 3 about the
- 9 meeting --
- 10 A. Uh-huh.
- 11 Q. -- in April, '04, as of that date,
- 12 April 20th, 2004, do you recall whether anyone had
- 13 collected any documents at that point yet in
- 14 relation to the audit?
- 15 A. I don't believe I had. I can't speak to
- 16 whether anybody else did.
- 17 Q. Were you aware of anyone else having
- 18 collected documents at that time?
- 19 A. I don't know.
- 20 Q. If you look back at the first page of
- 21 Exhibit 3 --
- 22 A. Okay.
- Q. -- there is a list of people in the to --
- A. Uh-huh.

- 1 Q. -- line --
- 2 A. Yes.
- Q. -- of the e-mail.
- 4 Do you recall whether all of those
- 5 individuals attended the meeting?
- 6 A. I know that Ken Stiles did attend, I
- 7 believe Amy Potthoff attended, I believe Rich Pinto
- 8 did, but I'm not positive, and I don't recall one
- 9 way or the other about Tom Woidat.
- 10 Q. Do you recall any discussions with
- 11 Mr. Woidat about Schedule A or the audit generally?
- 12 A. I don't recall specifically about
- 13 Schedule A.
- 14 I do recall discussing plan and update
- 15 documents with Tom Woidat.
- 16 Q. What are plan and update documents?
- 17 A. I -- I really don't know. We have some
- 18 sort of plan and update schedule. Financial
- documents regarding development of products, that's
- 20 really not my area.
- 21 Q. Do you know what Mr. Woidat's position
- 22 was back in 2004 at Abbott?
- 23 A. I believe he was in GPRD finance, but I
- 24 don't know his specific position.

- 1 Q. Do you recall when your discussion with
- 2 Mr. Woidat was regarding plan and update documents?
- 3 A. Sometime after this, but I don't recall
- 4 specifically.
- 5 Q. Do you recall whether Mr. Woidat provided
- 6 you with any documents in relation to the audit?
- 7 A. I believe I collected binders from him.
- 8 I don't recall whether they were for the audit or
- 9 the litigation.
- 10 Q. Do you recall how many binders?
- 11 A. No.
- 12 Q. How did you keep track of what was for
- the litigation versus what was for the audit when
- 14 you were collecting documents?
- 15 A. Litigation documents were sent to the
- attorneys, audit documents went to the warehouse.
- 17 Other than that, I don't know.
- 18 Q. Did you keep a list?
- 19 A. I don't believe so.
- Q. As best you can recall, what was
- 21 discussed at the meeting on April 20th, 2004?
- 22 And, again, I understand Mr. Wittenberg
- 23 was present. I'm not looking for anything in
- relation to legal advice, so exclude that from your

- 1 answer. I'm looking for what you're going to do in
- 2 terms of producing, collecting documents, the
- 3 logistics of the audit.
- 4 MR. LORENZINI: And just to be clear, object on
- 5 the basis of attorney-client privilege and work
- 6 product.
- 7 To the extent you can recall, you know,
- 8 anything regarding logistics of who -- who would be
- 9 contacted or any next steps to take, you can
- 10 disclose that, but --
- 11 THE WITNESS: Okay.
- 12 MR. LORENZINI: -- don't reveal anything that
- would involve attorney-client legal communication.
- 14 BY THE WITNESS:
- 15 A. I recall two things.
- 16 I recall Ken Stiles --
- 17 MR. LORENZINI: Okay.
- 18 BY THE WITNESS:
- 19 A. -- discussing the location of the
- timesheets and I recall Amy Potthoff was either
- asked to or volunteered to provide names of people
- to begin contacting.
- 23 BY MS. COLLARI TROAKE:
- Q. And those names we have already gone

- 1 through, correct?
- 2 A. Yeah, I believe -- yes, I believe we --
- 3 Q. Chris Sopata, Richard Herst, and Rhonda
- 4 Rickey?
- 5 A. Those are the names I remember, yes.
- 6 Q. Anything else you can recall about that
- 7 meeting?
- 8 A. No.
- 9 Q. Were you assigned specific tasks in the
- 10 course of that meeting?
- 11 A. I don't remember. I don't believe I was
- 12 assigned specific tasks, but I really don't remember
- 13 the meeting.
- 14 Q. Do you recall whether anyone else was
- asked to take specific actions in the course of that
- 16 meeting?
- 17 A. I recall Ken Stiles was going to follow
- up on the timesheets and I recall Amy Potthoff was
- 19 going to provide names of people to begin
- 20 contacting.
- 21 Q. Other than that, do you recall anything?
- 22 A. No.
- 23 Q. Do you recall why Mr. Stiles was being
- 24 asked to look for the timesheets?

- 1 A. I believe he knew where they were, and
- 2 they were on the schedule.
- 3 Q. Anything else?
- 4 A. I didn't ask him to do it, I believe that
- 5 was Ken, so I don't know why he was asked.
- 6 Ken Wittenberg. Sorry. Two Kens.
- Q. Was there any discussion about how long
- 8 it would take to collect the information that was
- 9 outlined in Schedule A in the course of this
- 10 meeting?
- 11 A. Not that I remember.
- 12 Q. Was there any discussion about how best
- 13 to collect that information that was called for by
- 14 Schedule A and make that available to John Hancock's
- 15 auditors?
- 16 MR. LORENZINI: Objection. I think this --
- 17 that will call for disclosure of attorney-client
- 18 privileged communication, perhaps.
- 19 BY THE WITNESS:
- 20 A. Not that I re --
- 21 MR. LORENZINI: I instruct the witness not to
- 22 answer.
- 23 THE WITNESS: Okay.
- 24 BY MS. COLLARI TROAKE:

- 1 Q. Other than this meeting on April 20th,
- 2 2004, with these individuals, were there any
- 3 subsequent meetings of these individuals or a subset
- 4 of these individuals in relation to the audit?
- 5 A. I don't know.
- 6 Q. Did you participate in any other meetings
- 7 with any of these individuals in relation to the
- 8 audit?
- 9 A. I had discussions with them, as we've
- 10 already talked about. I don't know if they had
- 11 meetings with Ken or otherwise.
- 12 Q. Ken --
- 13 A. Wittenberg.
- 14 Or amongst themselves.
- 15 Q. Other than the individuals at this
- 16 meeting and the list we've already --
- 17 A. Uh-huh.
- 18 Q. -- gone through, who else was involved in
- 19 the collection of documents in relation to the
- 20 audit?
- 21 A. Huh.
- l'm just thinking.
- 23 MR. LORENZINI: I'm going to object on the
- 24 grounds of vagueness and ambiguity.

- 1 BY THE WITNESS:
- 2 A. I'm just thinking.
- 3 BY MS. COLLARI TROAKE:
- 4 Q. You can answer.
- 5 A. I'm just thinking.
- We've discussed these people, the people
- 7 contacted. Someone in Ken's group, I don't recall
- 8 who, we talked about that, people at the RIC, people
- 9 at corporate records.
- 10 Q. And who is -- who are the people at the
- 11 RIC?
- 12 A. There's only one person I know
- 13 specifically.
- 14 Q. And who's that?
- 15 A. Frank Pavelske, P-a-v-e-l-s-k-e.
- 16 Q. And who was he?
- 17 A. He worked at the RIC. I don't know his
- 18 title.
- 19 Q. Do you know what his responsibilities
- were at the RIC?
- A. He -- at the RIC, no, I don't.
- Q. I'm sorry.
- Okay. So after the RIC you were saying
- 24 corporate records?

- 1 A. Yes.
- 2 Q. Do you know who at corporate records was
- 3 involved?
- 4 A. I believe John Deram, D-e-r-a-m, but I'm
- 5 not positive.
- 6 That's the only person I can recall at
- 7 corporate records working on pulling files.
- 8 Q. Okay. So anyone else other than those
- 9 two in addition to the ones we've already talked
- 10 about?
- 11 A. That were involved in collecting
- 12 documents.
- 13 I can't really recall anybody other than
- the people that we have sort of gone over throughout
- 15 this.
- 16 Q. How about John Moore?
- 17 A. John Moore was in licensing. I collected
- 18 from him.
- 19 Q. What did you collect from him?
- A. His documents related to outlicensing or
- 21 new business development -- I'm not certain --
- related to the compounds.
- 23 Q. Do you know what categories on Schedule A
- 24 Mr. Moore's documents related to?

- 1 A. The only one I can say specifically would
- 2 be 3-F because he worked in outlicensing.
- 3 Other than that, I don't know what other
- 4 documents he had in his files related to the
- 5 compounds.
- 6 Q. Okay. Did you do any review of his
- 7 documents prior to making them available to the
- 8 auditors to determine what other categories of
- 9 Schedule A might have been satisfied by the
- 10 documents provided by Mr. Moore?
- 11 A. Did I?
- 12 No.
- 13 Q. Do you know if anyone else at Abbott did
- 14 that?
- 15 A. I don't believe so, no.
- 16 Q. What about Sue Kuras?
- 17 I'm not -- not sure I'm pronouncing it
- 18 correctly.
- 19 A. Yeah.
- 20 Q. Kuras.
- 21 A. Kuras.
- 22 She's an administrative assistant. I
- 23 don't know what role she played.
- Q. Anyone else that was involved in

- 1 collecting documents?
- 2 MR. LORENZINI: Objection.
- 3 I -- I just want to clarify. Do you mean
- 4 people involved in -- the collectors or the
- 5 collectees?
- 6 You're just re -- referring to the people
- 7 doing the collection?
- 8 MS. COLLARI TROAKE: Yes.
- 9 MR. LORENZINI: Okay. Not the people providing
- documents, but the people collecting.
- 11 MS. COLLARI TROAKE: I'll get to that.
- 12 MR. LORENZINI: Okay.
- 13 BY THE WITNESS:
- 14 A. Okay. I don't -- I guess I don't lump
- 15 John Moore into a person collecting documents --
- 16 BY MS. COLLARI TROAKE:
- 17 Q. You put him in the providing category.
- 18 A. Providing documents.
- 19 Q. Okay.
- A. People collecting documents, there's
- 21 nobody else that I can recall other than people
- we've discussed.
- Q. Now, in terms of those people who
- 24 provided documents --

- 1 A. Uh-huh.
- 2 Q. -- in response to efforts to collect,
- 3 other than the people we've already listed, who else
- 4 do you recall who provided documents in relation to
- 5 the audit?
- 6 A. Steve Mickel, M-i-c-k-e-l, Michele Parks,
- 7 Tony Deahl -- I believe it's D-e-a-h-l -- Kevin
- 8 Constable -- I'm thinking -- Stan Bukofzer,
- 9 B-u-k-o-f-z-e-r, I think.
- 10 Oh, there is a name I can't remember. He
- 11 worked in finance and he pulled extracts -- he
- 12 pulled extracts. I think it was from a system
- 13 called -- I think it's called R/OSS, but I don't
- 14 remember his name.
- 15 Q. When you said "he pulled extracts," what
- 16 does that mean?
- 17 A. I believe he pulled extracts from a
- 18 database.
- 19 And I think the system was called R/OSS.
- 20 I'm not positive.
- Q. Do you know what type of information was
- on that system?
- A. I believe it was expenditures related
- 24 to -- I'm guessing. I believe it was related to

- 1 outsourcing, contractors. I believe that's what --
- 2 it was financial information related to work done on
- 3 the compounds, but I believe it was related to
- 4 outside people.
- 5 Q. And you didn't recall his name?
- 6 A. No.
- 7 Q. Do you recall when that person --
- 8 A. His name -- I'm sorry.
- 9 Q. Go ahead.
- 10 A. His name might have been Brown, something
- 11 Brown, that's --
- 12 Q. Okay.
- A. I'm trying to picture it.
- 14 Q. Do you recall when this financial person,
- who may be named Brown, provided this information to
- 16 you?
- 17 A. Sometime between this meeting and the
- 18 meeting with the attorneys at the Mundelein
- 19 warehouse.
- Q. And the meeting with the attorneys at the
- 21 Mundelein warehouse, are you referring to the
- 22 December 17th meeting?
- A. I don't know the date, but there was only
- 24 one meeting at the Mundelein warehouse with the

- 1 attorneys.
- 2 Q. Was that the meeting where Brian Davis
- 3 from Choate, Hall & Stewart was present, Steve
- 4 D'Amore from Winston & Strawn, you were present?
- 5 A. Steve D'Amore, Chris Martinez -- I
- 6 believe it was Brian Davis, I'm not certain -- and
- 7 myself.
- 8 Q. Okay. So sometime between April and
- 9 December of '04 these documents were provided by
- this financial person.
- 11 A. This is -- yeah. Yes.
- 12 Q. Okay. Anyone else that you can recall
- 13 who provided documents?
- 14 MR. LORENZINI: Objection. Vague and ambiguous
- 15 as to --
- 16 BY THE WITNESS:
- 17 A. No, I really --
- 18 MR. LORENZINI: -- "anyone else," the phrase
- 19 "anyone else."
- 20 BY THE WITNESS:
- 21 A. I'm really -- I really can't remember
- 22 anybody else.
- 23 BY MS. COLLARI TROAKE:
- Q. Do you recall whether Michael Meyer

- 1 provided documents in relation to the audit?
- 2 MR. LORENZINI: Objection. Vague and
- 3 ambiguous.
- 4 BY THE WITNESS:
- 5 A. No.
- 6 MR. LORENZINI: You're referring to personally
- 7 providing it, providing documents?
- 8 MS. COLLARI TROAKE: I don't know what you mean
- 9 by "personally."
- 10 MR. LORENZINI: As opposed to his documents
- 11 being in some other location.
- 12 BY MS. COLLARI TROAKE:
- 13 Q. Why don't I try to rephrase it.
- 14 Do you know whether Michael Meyer
- 15 provided documents that were made available to the
- 16 auditors?
- 17 A. I don't know.
- 18 Q. Do you know whether Elizabeth Kowaluck
- 19 provided documents that were made available to the
- 20 auditors?
- A. I don't know.
- 22 Q. Do you know whether Lise Loberg provided
- 23 documents that were made available to the auditors?
- A. No, I don't know.

- 1 Q. What about Chris Silber?
- 2 The same question.
- 3 A. I don't know.
- 4 Q. Just to make this go a little bit
- 5 faster --
- 6 A. Sure.
- 7 Q. -- I'm going to ask you this exact same
- 8 question, I'm just going to give you the person's
- 9 name --
- 10 A. Okay.
- 11 Q. -- and you tell me whether you know
- 12 whether they provided documents that were made
- 13 available to the auditors.
- 14 A. Okay.
- 15 Q. Okay. All right. Angela Landsberg?
- 16 A. I don't know.
- 17 Q. Bruce McCarthy?
- 18 A. I don't recall.
- 19 Q. Azmi Nabulsi?
- A. I don't know.
- 21 Q. James Looman?
- A. I don't know.
- 23 Q. Michael Biarnesen?
- 24 A. Biarnesen.

- 1 Q. Biarnesen.
- 2 A. I don't know.
- 3 Q. Jeffrey Leiden?
- 4 A. I don't recall.
- Q. Jim Thomas?
- 6 A. I don't know.
- 7 Q. Carol Meyer?
- 8 A. Yes.
- 9 Q. Do you recall what documents Ms. Meyer
- provided that were made available to the auditors?
- 11 A. No.
- 12 Q. Were you the person who collected those
- documents from Ms. Meyer?
- 14 A. They were provided to me, and I provided
- them to the auditors -- to the warehouse.
- 16 Q. Do you know when you did that?
- 17 A. No.
- 18 Q. Was it sometime between April, '04, and
- 19 the meeting in December?
- A. That I don't remember.
- 21 Q. Do you recall the volume of documents
- 22 provided by Ms. Meyer?
- 23 A. No.
- Q. Do you recall it being on a CD or in

- 1 documents were made available to the auditors what
- 2 categories on Schedule A Ms. Meyers' documents
- 3 related to?
- 4 A. I don't believe so, no.
- 5 Q. Do you know whether William Dempsey
- 6 provided documents that were made available to the
- 7 auditors?
- 8 A. I don't know.
- 9 Q. What about Tom Woidat?
- 10 Other than what we've already discussed.
- 11 A. Other than what we've already discussed?
- 12 I don't recall.
- 13 Q. What about John Leonard?
- 14 A. I don't know.
- 15 Q. Brian Smith?
- A. I don't believe so. He's an attorney. I
- don't recall collecting anything from him.
- 18 Q. James Tyree?
- A. I believe the letters were provided to
- 20 the auditors.
- 21 Q. What letters?
- A. The communications, Tyree's letter, there
- 23 were some letters early on in the beginning, I
- 24 believe Tyree's name was on it.

- 1 Other than that, I don't know if he
- 2 provided anything.
- 3 Q. What about Tom Lyons?
- 4 A. Again, perhaps the letters. Other than
- 5 that, I don't know.
- 6 There were communications early on in the
- 7 first case that may have been in the audit
- 8 documents. I don't remember.
- 9 Q. Anything else other than that?
- 10 A. Anything else other than the letters?
- 11 Letters and any supporting documents
- 12 attached to the letters.
- No, I don't remember.
- 14 Q. Were you the person who collected those
- 15 documents from Mr. Lyons?
- A. I believe -- I believe I did collect them
- at one point, yes.
- 18 Q. And do you know in what form they were
- 19 provided to you?
- A. I believe it was electronically.
- 21 And I don't know if it was specifically
- 22 provided to me.
- 23 Q. If it wasn't provided to you, who would
- 24 it have been provided to?

- 1 if I really read them or reviewed them.
- 2 Q. Did you -- did you review them in any way
- 3 to make a determination as to what categories they
- 4 related to on Schedule A?
- 5 A. On Schedule A?
- 6 I don't believe so, but I don't remember.
- 7 Q. Do you know if anyone else undertook that
- 8 task?
- 9 A. I don't know.
- 10 Q. Did Mr. Lyons indicate to you what he
- 11 thought his documents related to in reference to
- 12 Schedule A?
- A. I don't believe so, but I don't remember
- 14 specifically or generally.
- 15 Q. Do you know whether Don Buehl provided
- documents that were made available to the auditors?
- 17 A. I don't remember.
- 18 Q. What about Steve Weger, W-e-g-e-r?
- A. I don't know that name, so I don't
- 20 remember.
- 21 Q. Philip Deemer?
- A. I don't recall.
- 23 Q. Marilyn Colicott?
- A. I don't recall.

- 1 Q. Diane D'Amico?
- A. I don't recall.
- 3 Q. What about Patricia Hintzman?
- 4 A. I don't know that name, so I don't know.
- 5 Q. Bob Hanson?
- 6 A. I don't know that name, so I don't know.
- 7 Q. Diane Bronson?
- 8 A. I think I've heard that name, but I don't
- 9 know.
- 10 Q. In relation to collecting documents for
- the audit, is there -- let me step back.
- 12 Is there something in Abbott that's like
- a web-based storage facility for documents? Does
- 14 that sound familiar?
- 15 A. I believe there are lots of web-based
- document houses at Abbott. I don't know -- I don't
- 17 know if they're storage facilities. I believe there
- are many, many of them.
- Q. Did you search those web-based storage
- 20 houses, as you described them, in relation to
- 21 collecting documents for the audit?
- A. I searched certain locations as they were
- 23 identified for documents pertaining to the
- 24 compounds.

- 1 Q. Do you recall which locations you search?
- 2 A. The ones I recall are GPRD finance shared
- drive, port analysis shared drive -- that's p-o-r-t
- 4 analysis -- MPSR database, which is monthly project
- 5 status report.
- 6 There -- I don't recall specifically.
- 7 There was some sort of website or one or more
- 8 websites for oncology. I believe there might have
- 9 been one for neuroscience, but I don't remember
- 10 specifically.
- 11 Is there anything else?
- Web-based -- actually, that's incorrect.
- Not all of those are web-based.
- 14 So web-based, I believe oncology had a
- web-based portal or database, maybe more than one,
- and I believe one of the other therapeutic areas
- did, and I searched them.
- 18 Q. And what were the others if they were not
- 19 web-based?
- A. The shared drives are -- I don't know the
- 21 technical terms. They're shared drives.
- I believe the MPSR database is a
- 23 Lotus Notes-based database.
- I think that's the categories they fall

- 1 into. I don't remember anything else.
- 2 Q. Okay. So other than the ones you have
- 3 listed, any other web-based facilities, shared
- 4 drives, or databases that you searched?
- 5 A. I searched a system -- I believe it's
- 6 web-based -- called Optika.
- 7 That I personally searched?
- 8 Q. Well, we'll start with that --
- 9 A. Okay.
- 10 Q. -- that you personally searched.
- 11 A. That's the only one I can think of.
- 12 Q. That you personally searched.
- 13 A. Yes.
- Q. The other ones that you mentioned that
- 15 were searched?
- A. The only one I can think of was the R/OSS
- 17 system that we -- someone name Brown pulled data
- from. That's the other one I can think of.
- 19 Q. Any other databases, web-based
- 20 facilities, shared drives that were searched, either
- 21 by you or someone else?
- A. Not that I remember, but I think they're
- outlined in the 30(b)(6) response. That might
- provide more detail. I just don't remember.

- 1 Q. Now, going back to the list of people who
- 2 provided documents, you mentioned Steve Mickel.
- 3 A. Yes.
- 4 Q. Do you recall when he provided documents?
- 5 A. No.
- 6 Q. Do you recall what kinds of documents he
- 7 provided?
- 8 A. He worked in outlicensing and new
- 9 business development, so I believe they were
- 10 outlicensing and new business development documents
- 11 pertaining to the compounds.
- 12 Q. Do you know in what form he provided
- 13 those documents?
- 14 A. I believe it was paper. And I think he
- printed e-mails for me.
- He did print e-mails for me.
- 17 Q. I'm sorry?
- 18 A. He did print at least one e-mail that I
- 19 know of for me.
- 20 Q. Did you undertake a review of his
- 21 documents prior to them being made available to the
- 22 auditors?
- A. I did not review them.
- Q. Do you know if anyone else reviewed

- 1 them --
- 2 A. Yes.
- 3 Q. -- prior to them being made available to
- 4 the auditors?
- 5 A. Sorry.
- 6 Yes.
- 7 Q. Do you know who that was?
- 8 A. Specifically, no.
- 9 Q. Generally?
- 10 A. Winston & Strawn.
- 11 Wait. You know, can I clarify something?
- 12 Q. Sure.
- A. I believe some things were provided to
- the auditors from Steve and I believe other things
- 15 were reviewed first.
- 16 I think -- I think that's how it went
- 17 with Steve's documents.
- 18 Q. Do you have a recollection as to what was
- 19 provided directly to the auditors versus what was
- 20 reviewed first?
- A. The only thing I specifically recollect
- was a binder called Project Odin, O-d-i-n.
- Q. In which category did the Project Odin
- 24 binder fall into?

- 1 A. I didn't read it. It has something to do
- with outlicensing of one of the compounds.
- Q. Let me clarify.
- 4 The Project Odin binder, was it reviewed
- 5 first or made available --
- 6 A. Oh.
- 7 Q. -- to the auditors directly?
- 8 A. I apologize.
- 9 That was made available directly.
- 10 Q. Do you recall when that was?
- 11 A. No.
- 12 Q. Do you know if the review by Winston &
- 13 Strawn encompassed -- encompassed an analysis of
- 14 what categories in Schedule A Mr. Mickel's documents
- 15 related to?
- 16 A. I can't speak to what Winston & Strawn
- 17 did.
- 18 Q. So you don't know.
- 19 A. I can't speak to it. I don't know what
- 20 they did.
- 21 Q. Did you do any analysis of his documents
- 22 to determine what categories on Schedule A those
- 23 documents related to?
- A. I believe I just provided them to

- 1 might have precipitated Winston & Strawn's review of
- 2 documents before they were made available to the
- 3 auditors?
- 4 MR. LORENZINI: Objection. It calls for
- 5 attorney-client privilege and work product.
- 6 I instruct the witness not to answer.
- 7 BY MS. COLLARI TROAKE:
- 8 Q. What kinds of documents did Ms. Parks
- 9 provide?
- 10 A. I believe she provided CDAs, but I'm not
- 11 positive. I believe that's what she provided.
- 12 Q. Any relation to outlicensing? Is that
- 13 what you said?
- A. She's in the outlicensing department,
- outlicensing and new business development.
- 16 Q. With respect to Tony Deahl, what
- 17 department was he in?
- 18 A. Same department, same general area.
- 19 I don't recall the specific title of the
- department.
- 21 Q. But outlicensing new business
- 22 development?
- A. That's what I called them.
- Q. And when did Mr. Deahl provide documents

- 1 in relation to the audit?
- 2 A. I don't know.
- 3 Q. Do you know whether his documents were
- 4 reviewed by Winston & Strawn before they were made
- 5 available to the auditors?
- 6 A. I don't know.
- 7 Q. Did you review his documents prior to
- 8 them being made available to the auditors?
- 9 A. I don't remember.
- 10 Q. Do you recall reviewing his documents at
- 11 any point to determine what categories on Schedule A
- 12 his documents related to?
- 13 A. No, I don't recall doing that.
- 14 Q. Do you recall in what form Mr. Deahl
- 15 provided his documents?
- 16 A. No.
- 17 Q. What about Kevin Constable?
- 18 A. Yes.
- 19 Q. What department was he in?
- A. I don't know if he was in that department
- at the time. At one point he was in the same
- department as the others. I don't recall what
- department he was in when I contacted him.
- Q. How did you contact him?

- 1 A. I don't remember. Most likely phone or
- 2 e-mail.
- 3 Q. And what kinds of documents did he
- 4 provide?
- 5 A. I don't know specifically. Something to
- do with outlicensing or new business development
- 7 related to the compounds in the research funding
- 8 agreement.
- 9 Q. And at what point in time did he provide
- 10 those documents?
- 11 A. I don't remember.
- 12 Q. Did you review his documents before they
- were made available to the auditors to determine
- 14 what categories on Schedule A his documents related
- 15 to?
- 16 A. I don't remember doing that.
- 17 Q. Do you know if anyone else reviewed them
- 18 for that purpose?
- 19 A. Not that I know of, but I'm not sure.
- 20 Q. Did Winston & Strawn review his documents
- 21 before they were made available to the auditors?
- 22 A. I'm not certain. It's possible.
- 23 Q. You said Stanley Bukofzer provided
- 24 documents?

- 1 A. Bukofzer, yes.
- 2 Q. What department was he in?
- A. He's a physician, and he was in -- had
- 4 something to do with the development of one of the
- 5 compounds. I don't know if it was at the time we
- 6 contacted -- I contacted him or Ken Wittenberg
- 7 contacted him.
- 8 Q. Or Ken --
- 9 A. Wittenberg contacted him. I don't
- 10 remember who actually did.
- 11 Q. Do you know if it was a compound referred
- to as ABT-773 that Mr. Bukofzer was working on?
- A. I'm not positive. I do believe he worked
- 14 on 773.
- 15 Q. Do you recall when Mr. Bukofzer provided
- 16 his documents?
- 17 A. No.
- 18 Q. Do you recall reviewing his documents
- 19 before they were made available to the auditors?
- 20 A. No.
- Q. Do you recall reviewing them in any way
- 22 to make a determination as to what categories in
- 23 Schedule A they related to?
- 24 A. No.

- 1 Q. Do you know if Winston & Strawn reviewed
- 2 those documents before they were made available to
- 3 the auditors?
- 4 A. I don't recall specifically, but I don't
- 5 believe so.
- 6 Q. Do you know in what form Mr. Bukofzer
- 7 provided his documents?
- 8 A. The documents I recall were paper.
- 9 Q. Do you recall the volume?
- 10 A. I believe it was a box, that I can
- 11 remember. I remember a box.
- 12 Q. A banker's box or --
- 13 A. A, yeah, standard copy box.
- 14 Q. With respect to the individuals that
- we've talked about who provided documents, do you
- 16 know if anyone undertook any analysis to determine
- 17 what -- what categories on Schedule A their
- 18 documents related to?
- 19 MR. LORENZINI: Objection. It calls for
- 20 speculation.
- 21 MS. COLLARI TROAKE: I'm asking if she knows.
- 22 BY THE WITNESS:
- A. No, I don't know.
- 24 BY MS. COLLARI TROAKE:

- 1 Q. Did you undertake any kind of analysis in
- 2 that regard to determine what categories on
- 3 Schedule A these documents related to?
- 4 A. I believe 3-F says all documents
- 5 pertaining to the actual or attempted outlicensing
- 6 or divestiture of -- oh, no. That's ceased
- 7 compounds.
- 8 Somewhere in there is -- I believe that
- 9 they worked in outlicensing and they worked on the
- 10 compounds. I don't know that I did any analysis. I
- 11 believe that was the category they fell into, so I
- 12 asked for any documents they had related to the
- 13 compounds.
- 14 Q. So you didn't identify a particular
- 15 category on Schedule A.
- 16 A. I don't think so. I don't recall doing
- that. And it's not refreshing my memory, so I don't
- 18 know.
- 19 Q. In relation to outlicensing and the
- 20 program compounds, were there any other individuals
- who provided documents that were made available to
- the auditors?
- A. I'm thinking out loud.
- 24 Tony Deahl, Kevin Constable, Steve

- 1 Mickel, John Moore. Those are the ones I remember.
- 2 Q. And other than those individuals, did
- 3 anyone else provide documents that were made
- 4 available to the auditors other than what we've
- 5 already talked about?
- 6 A. Huh.
- 7 I don't remember specifically anybody
- 8 other than the people we've talked about.
- 9 Q. Now, you said you specifically remembered
- that the Project Odin binder provided by Steve
- 11 Mickel --
- 12 A. Uh-huh.
- 13 Q. -- had been made available to the
- auditors without any prior review.
- 15 Is that right?
- 16 A. Without any prior review by the
- 17 attorneys, yes.
- 18 Q. Okay. Can I ask why you remember that
- 19 binder in particular?
- 20 A. Because they wanted it copied and --
- Q. Who wanted it copied?
- A. The auditors asked that it be copied, and
- 23 I remember providing it to Ken Wittenberg to take a
- 24 look at for potential privilege issues.

- 1 BY MS. COLLARI TROAKE:
- 2 Q. And you said that you provided it to Ken
- 3 Wittenberg for him to review for privilege issues?
- 4 A. Potential privilege issues.
- 5 Q. Do you know what prompted you to ask him
- 6 to look at it for that purpose?
- A. I really don't remember. I looked at it,
- 8 and I thought he should take a look at it, but I
- 9 don't remember why specifically.
- 10 Q. Do you recall whether that particular
- binder was subsequently provided to the auditors?
- 12 A. It was provided to the auditors, a copy
- of it was provided, at some point.
- 14 Q. Do you recall whether any of it was
- 15 withheld --
- 16 A. I don't know.
- 17 Q. -- on privilege grounds?
- 18 A. I'm sorry.
- 19 No, I don't know.
- Q. Did you provide the copy to the auditors?
- A. I don't know.
- 22 Q. You don't know or you don't recall?
- A. I don't know.
- 24 I know it was provided. I don't know if

- 1 Q. Do you recall who those discussions were
- 2 with?
- 3 A. I'm thinking.
- 4 Ken Wittenberg. Perhaps Winston &
- 5 Strawn, but I don't recall specifically or
- 6 specifically who at Winston.
- 7 Q. Anyone else?
- 8 A. I don't believe so, no.
- 9 Q. Did you do any research into the
- 10 background of StoneTurn or Mr. Martinez or
- 11 Mr. Napper in this time frame?
- 12 MR. LORENZINI: Hold for a second.
- 13 THE WITNESS: Sure.
- 14 MR. LORENZINI: You can answer yes, no.
- 15 BY THE WITNESS:
- 16 A. I looked them up on the Internet.
- 17 BY MS. COLLARI TROAKE:
- 18 Q. Did you find anything?
- 19 MR. LORENZINI: I'm going to object and
- 20 instruct the witness not to answer on the grounds of
- 21 attorney-client privilege and work product.
- MS. COLLARI TROAKE: We are up to 7.
- 23 (WHEREUPON, a document was marked
- 24 Campbell Exhibit No. 7, for

- 1 identification, as of 2/20/07.)
- 2 BY MS. COLLARI TROAKE:
- 3 Q. Ms. Campbell, I put in front of you
- 4 what's been marked as Exhibit 7.
- 5 Do you recognize that document?
- A. Can I look at it --
- 7 Q. Yes.
- 8 A. -- first?
- 9 Q. Yeah.
- 10 A. Thank you.
- 11 (WHEREUPON, there was a short
- 12 interruption.)
- 13 BY THE WITNESS:
- A. I believe I've seen it in preparation. I
- don't recall seeing it other than that.
- 16 BY MS. COLLARI TROAKE:
- 17 Q. All right. So you don't recall seeing a
- 18 copy of it at around the time that it was apparently
- 19 written, May 10th, 2004?
- A. No, I don't recall.
- 21 Q. If you could turn to the second page
- of that letter, the last paragraph, beginning
- 23 "Finally" -- do you see that?
- 24 A. Yes, I see it.

- 1 Q. Still looking at Exhibit --
- 2 A. Sure.
- 3 Q. -- 7, at the bottom of the first page,
- 4 beginning "For example" --
- 5 A. Okay.
- 6 Q. -- it says, "...Hancock has requested
- 7 each and every invoice, purchase order and payroll
- 8 record relating to a project involving hundreds of
- 9 millions of dollars of expenditures," and it says,
- 10 "Abbott has determined that just one small portion
- 11 of just this one request (of a total of 30 requests
- 12 by Hancock) involves approximately 24 boxes of
- 13 timesheets alone."
- Does that refresh your recollection as to
- when you may have had your conversation with
- 16 Mr. Stiles about the timesheets, bearing in mind the
- 17 letter is dated May 10th, 2004?
- 18 A. Okay. No. As I said, I think it was
- around the time of the initial meeting, but I -- no.
- Q. And do you recall whether this number,
- 21 24 boxes of timesheets, whether that was -- that's
- an accurate count of how many boxes related to
- 23 timesheets?
- A. I don't recall the number, but I don't

- 1 have any reason to not believe what's written. But
- 2 I don't recall specifically the number of boxes.
- 3 Q. If you could go back to Exhibit 2 for a
- 4 moment, please --
- 5 A. Sure.
- 6 I have got them out of order. 4, 3, 2.
- 7 Q. It's the letter to Mr. Tyree.
- 8 A. Okay.
- 9 Q. On the second page of the letter,
- 10 Bates No. 11184 --
- 11 A. Okay.
- 12 Q. -- the paragraph beginning "John
- 13 Hancock's inspection and audit" -- do you see that?
- 14 A. I see it, yes.
- 15 Q. And the second sentence of that says,
- 16 "The audit shall take place during normal business
- 17 hours commencing on May 12, 2004, and continuing
- 18 from day to day thereafter until completion," and it
- 19 continues on.
- 20 Do you see that?
- A. I see that, yes.
- Q. Do you have any recollection of being
- 23 informed that the audit was scheduled to begin
- 24 sometime around May 12, 2004?

- 1 A. I don't specifically remember that, but
- 2 this appears to be a letter stating that that is a
- date that Choate or Hancock is choosing.
- 4 I don't know that that was the date it
- was scheduled to begin, but I don't remember when it
- 6 was scheduled to begin, either.
- 7 Q. Do you recall any discussion about that
- 8 being a date that Abbott was working towards to
- 9 produce and make available documents to the
- 10 auditors?
- 11 MR. LORENZINI: I'm going to object that that
- 12 potentially calls for attorney-client privileged
- 13 communications.
- 14 You can answer yes or no.
- 15 BY THE WITNESS:
- A. I don't remember. I don't think so, but
- 17 I don't remember.
- 18 BY MS. COLLARI TROAKE:
- 19 Q. If you could go back to Exhibit -- it's
- 20 the April 20th meeting e-mail.
- 21 A. Sure.
- 22 Q. I can't remember what number it was.
- A. I think it was 3.
- 24 Q. 3.

- 1 Q. Yeah.
- The last entry there is a 24 Seven copy
- 3 vendor.
- 4 A. Yes.
- 5 Q. Is that the copier that you used to copy
- all the documents in relation to the audit?
- 7 A. That's the service that we used. And I
- 8 believe they copied the majority of them. I don't
- 9 remember if they copied everything.
- 10 Q. And the individual that you dealt with
- there, was his name Jim Wendrickx?
- 12 A. That's generally who I deal with, my
- 13 contact person.
- 14 Q. And do you recall what your process was
- with respect to arranging for things to be copied?
- A. I recall specifically that Jim was
- 17 picking up things at the RIC, Research Information
- 18 Center, and I believe -- I don't recall
- 19 specifically -- I believe he was bringing them
- 20 directly to Mundelein and returning originals to the
- 21 RIC.
- Other than that, I can only speak
- 23 generally that I send e-mails or leave voice mails.
- 24 He works on many different projects, so I

- 1 would generally send him an e-mail or voice mail,
- 2 I need this picked up, blah, blah, blah -- I'm sorry
- 3 to do that -- you know, I need this picked up from
- 4 me or we need to go to somebody's office or we need
- 5 to go to wherever.
- 6 Q. Do you recall when the first time you
- 7 contacted him with respect to the audit material?
- 8 A. I don't recall the date.
- 9 I believe the first thing he started
- 10 working on were Research Information Center
- 11 documents.
- 12 (WHEREUPON, a document was marked
- 13 Campbell Exhibit No. 9, for
- identification, as of 2/20/07.)
- 15 BY MS. COLLARI TROAKE:
- 16 Q. Ms. Campbell, I put in front of you
- 17 what's been marked as Exhibit 9.
- 18 A. Yes.
- 19 Q. If you would take a moment to look at
- that e-mail string and let me know whether you
- 21 recognize it.
- 22 A. Okay.
- 23 (WHEREUPON, there was a short
- 24 interruption.)

- 1 materials.
- 2 Do you recall at all what those materials
- 3 were and where they came from?
- 4 A. I don't recall specifically, but AP34 is
- 5 the location -- was the location, it may still be,
- 6 for licensing and new business development, but I
- 7 don't recall specifically what they were.
- 8 It's also a location for a lot of other
- 9 people and departments.
- 10 Q. Uh-huh.
- 11 What about AP6?
- 12 A. AP6 is my building.
- 13 Q. Is there any other document that you
- 14 could look at that would remind you or refresh your
- 15 recollection about what was in that binder or those
- 16 boxes?
- 17 A. Not that I can think of. I don't know.
- 18 Q. And do you recall what categories on
- 19 Schedule A that binder or those boxes related to?
- A. Unfortunately, if I can't recall what
- 21 they were, I can't recall what they would be on
- 22 Schedule A.
- 23 (WHEREUPON, a document was marked
- 24 Campbell Exhibit No. 10, for

- 1 identification, as of 2/20/07.)
- 2 BY MS. COLLARI TROAKE:
- 3 Q. Ms. Campbell, I have put in front of you
- 4 what's been marked as Exhibit 10. Can you take a
- 5 look at it, please, and let me know whether you
- 6 recognize it.
- 7 A. Yeah.
- 8 Yes, I can take a look at it.
- 9 (WHEREUPON, there was a short
- 10 interruption.)
- 11 BY THE WITNESS:
- 12 A. I don't specifically recognize it, but I
- have no reason to doubt that this is an e-mail from
- me to Jim.
- 15 BY MS. COLLARI TROAKE:
- 16 Q. Do you recall meeting Mr. Wendrickx at
- the RIC facility at or around that time, June 3rd,
- 18 '04, which I'll represent to you is a Thursday?
- 19 So we're talking about -- you're talking
- about meeting the following Tuesday, which was
- 21 June 8th.
- A. I don't recall the specific dates. I do
- recall meeting him at the RIC to discuss copying the
- 24 files.

- 1 Q. Okay. And the second sentence you have
- there says, "They will have boxes ready."
- Who is "they"?
- 4 A. The RIC.
- 5 Q. Anyone in particular?
- 6 A. Frank Pavelske.
- 7 Q. Anyone else?
- 8 A. He was my contact person.
- 9 Q. Do you know who he obtained documents
- 10 from?
- 11 A. From the warehouse storage of documents.
- 12 It's a facility.
- 13 I think he just --
- 14 Q. Pulled documents?
- 15 A. Pulled documents, yeah.
- 16 Q. Okay. Do you know how many boxes -- do
- 17 you recall how many boxes were available?
- 18 A. No. No, I don't.
- 19 Q. Do you recall what was in those boxes?
- MR. LORENZINI: Objection. Vague. Ambiguous.
- 21 BY THE WITNESS:
- A. I wouldn't know what was specifically in
- the boxes. I wasn't involved in pulling them.
- 24 BY MS. COLLARI TROAKE:

- 1 Q. Did you provide Mr. Pavelske with a copy
- 2 of Schedule A in order to -- did you provide him
- 3 with a copy of Schedule A?
- 4 A. I don't recall specifically, but I don't
- 5 believe so.
- 6 Q. Do you know if anyone else provided him
- 7 with a copy of Schedule A?
- 8 A. I don't know.
- 9 Q. In the second paragraph you say, "I will
- 10 have CDs coming, also."
- Do you recall what those CDs were in
- relation to and where they came from?
- A. I don't recall any details about them,
- but I was reviewing shared drives, and some of that
- information was being put on CDs to have the vendor
- 16 blow back.
- 17 Q. And blow back --
- 18 A. Print out.
- 19 Q. Print out.
- A. Yeah.
- 21 Q. Do you recall whether anyone was
- 22 reviewing the documents before they were given to
- 23 the copy vendor?
- A. I was looking at them on the drive and

- 1 moving them to disk.
- 2 Q. When you say "looking at them," were you
- 3 reading them and cataloging them in any way or were
- 4 you just taking a quick glance?
- 5 MR. LORENZINI: Objection. Objection to form.
- 6 You can answer.
- 7 BY THE WITNESS:
- 8 A. I was looking at them to determine if
- 9 they were -- if they pertained to the compounds.
- 10 BY MS. COLLARI TROAKE:
- 11 Q. Did you look at them to determine whether
- 12 they responded to any of the specific categories on
- 13 Schedule A?
- 14 MR. LORENZINI: Objection.
- 15 BY THE WITNESS:
- 16 A. I don't recall specifically doing that.
- 17 BY MS. COLLARI TROAKE:
- 18 Q. And with respect to the boxes from the
- 19 RIC facility --
- A. Uh-huh.
- 21 Q. -- did you undertake a review of those
- 22 documents before they were sent to the Mundelein
- 23 facility?
- 24 A. No.

- 1 MR. LORENZINI: Just let me know whenever you
- 2 want to take a break.
- 3 THE WITNESS: A few minutes.
- 4 MS. COLLARI TROAKE: 11, I think.
- 5 (WHEREUPON, a document was marked
- 6 Campbell Exhibit No. 11, for
- 7 identification, as of 2/20/07.)
- 8 BY MS. COLLARI TROAKE:
- 9 Q. Ms. Campbell, I put in front of you what
- 10 has been marked as Exhibit 11. If you could please
- take a look at that and let me know whether you
- 12 recognize that document.
- 13 (WHEREUPON, there was a short
- 14 interruption.)
- 15 BY THE WITNESS:
- A. I don't recall it specifically, but I
- 17 have no reason to doubt this is a communication
- 18 between myself and Jim.
- 19 BY MS. COLLARI TROAKE:
- Q. On the second page of the exhibit, which
- 21 is Bates numbered ABBT 126591 --
- 22 A. Yes.
- Q. -- you'll see there is an e-mail from you
- to Jim and you're requesting empty boxes and also

- 1 100 -- no -- 400 labels.
- 2 A. Yes.
- 3 Q. Do you see that?
- 4 What were the empty boxes for?
- 5 A. I don't know specifically. It says that
- 6 I wanted to put boxes picked up from records into
- 7 the same boxes as everything else, but I don't
- 8 remember specifically.
- 9 Q. Do you recall how you kept track of what
- 10 you were moving from one set of boxes to the other?
- A. I don't recall that I actually did that.
- 12 Q. Uh-huh.
- A. And I don't know -- if it was done, I
- don't know -- I don't recall tracking anything.
- 15 Q. Okay. What about the labels you were
- 16 requesting with the numbering on them? Do you
- 17 recall doing that?
- 18 A. Well, it -- it looks in here that we
- 19 requested it. It also asks for the cost before
- anything is done.
- 21 Q. Uh-huh.
- A. Other than that, I don't remember if
- 23 anything was done.
- Q. You don't recall actually labeling the

- 1 boxes 1 through 100 or whatever it turned out to be.
- 2 A. No. I don't recall specifically labeling
- 3 anything.
- 4 Q. Do you recall why you were requesting the
- 5 labels to be put on each box?
- 6 A. No, I really don't.
- 7 Q. In the first paragraph of that same
- 8 section of the e-mail it says, "I want to put the
- 9 boxes picked up from records."
- 10 Is that reference to records the RIC?
- 11 A. I believe it would be a reference to
- 12 corporate records. I'm not positive, but I believe
- 13 it would be.
- 14 (WHEREUPON, a document was marked
- 15 Campbell Exhibit No. 12, for
- identification, as of 2/20/07.)
- 17 BY MS. COLLARI TROAKE:
- 18 Q. Ms. Campbell, if you could take a look at
- 19 Exhibit 12, please, and let me know whether you
- 20 recognize that document.
- 21 A. Okay.
- 22 (WHEREUPON, there was a short
- 23 interruption.)
- 24 BY THE WITNESS:

- 1 A. I don't recognize the document
- 2 specifically, but I recognize the context of the
- 3 document and what was going on.
- 4 BY MS. COLLARI TROAKE:
- 5 Q. And what was the context of what was
- 6 going on?
- 7 A. At some point the RIC allowed us to take
- 8 originals to save some money, so we were going to
- 9 move originals -- prior to that I believe we were
- 10 copying everything -- and Jim offered to help us
- move them, or I asked him to.
- 12 Q. And in the e-mail at the bottom, which is
- 13 from you to Mr. Pavelske and Jim Wendrickx --
- 14 A. Yes.
- 15 Q. -- you say, "I agree with your idea to
- 16 move the boxes to Mundelein."
- 17 Did you have a conversation with
- 18 Mr. Pavelske about where to put the documents?
- A. I believe the audit was going on at
- 20 Mundelein, so I don't think we would have had a
- 21 conversation about where to put them. We were doing
- 22 it at Mundelein. I might have had a conversation
- with him.
- Q. If I could just stop you there, the date

- 1 Friday would have been June 11th.
- 2 A. It looks like it, yeah.
- 3 Q. Does that refresh your recollection that
- 4 you were aware that Abbott had agreed to produce
- 5 documents by June 11th?
- 6 MR. LORENZINI: Objection. Misleading. It
- 7 mischaracterizes the witness' prior testimony.
- 8 BY THE WITNESS:
- 9 A. It doesn't refresh my recollection, but I
- 10 have no reason to doubt that we started on the 11th.
- 11 I have no idea what Abbott agreed to prior to.
- 12 BY MS. COLLARI TROAKE:
- 13 Q. In the e-mail from Mr. Pavelske back to
- 14 you later -- I guess it's sent the next day,
- 15 June 10th --
- 16 A. Yeah.
- 17 Q. -- he says, "We'll give Jim 80 today and
- 18 send via Abbott delivery service another
- approximately 100 boxes hopefully this afternoon or
- 20 first thing Friday morning."
- 21 A. Yes.
- 22 Q. So it looks like Mr. Pavelske was talking
- about 80 -- 180 boxes, potentially.
- 24 Is that right?

- 1 MR. LORENZINI: Objection. Lacks foundation.
- 2 BY THE WITNESS:
- A. I don't remember it, but that's what it
- 4 says.
- 5 BY MS. COLLARI TROAKE:
- 6 Q. So do you recall that there were at least
- 7 180 boxes available at or around June 11, 2004, for
- 8 the auditors to begin reviewing?
- 9 A. I don't recall it specifically. I have
- no reason to doubt the e-mail, that the plan was to
- 11 deliver roughly 180 boxes.
- 12 Q. Do you recall at some point being
- 13 informed that Abbott was not going to make documents
- 14 available to the auditors on June 11th?
- 15 A. No.
- 16 Q. Do you recall at or around June 11th
- 17 telling Mr. Pavelske that things were on hold at the
- 18 moment?
- 19 A. No. I don't recall that.
- 20 MS. COLLARI TROAKE: 13.
- 21 (WHEREUPON, a document was marked
- 22 Campbell Exhibit No. 13, for
- identification, as of 2/20/07.)
- MR. LORENZINI: Would you like to take a break,

- 1 THE WITNESS: I need a break. If we can get to
- 2 a point --
- 3 MR. LORENZINI: Take a short break?
- 4 MS. COLLARI TROAKE: Yeah. That's fine.
- 5 THE VIDEOGRAPHER: We are going off the video
- 6 record at 1:41 p.m.
- 7 This concludes Tape No. 3.
- 8 (WHEREUPON, a recess was had.)
- 9 (WHEREUPON, a document was marked
- 10 Campbell Exhibit No. 14, for
- identification, as of 2/20/07.)
- 12 THE VIDEOGRAPHER: We are going back on the
- 13 video record at 1:50 p.m.
- 14 This is the beginning of Tape No. 4.
- 15 BY MS. COLLARI TROAKE:
- 16 Q. Ms. Campbell, do you recall at some point
- in mid to late June telling the copy vendor to stop
- 18 copying, to hold off on doing anything further for a
- 19 period of time?
- 20 A. No.
- Q. Would you take a look at Exhibit 14,
- which is in front of you, and let me know whether
- you recognize that document.
- 24 (WHEREUPON, there was a short

- 1 interruption.)
- 2 BY MS. COLLARI TROAKE:
- 3 Q. Do you recognize that document?
- 4 A. No, but I have no reason to doubt that
- 5 that's an e-mail trail between Jim and I.
- 6 Q. If you'll look at the second page, Bates
- 7 No. ABBT 190545, please, in the middle of that page
- 8 there's an e-mail from you, June 21st, it looks like
- 9 at 7:42 --
- 10 A. Okay.
- 11 Q. -- saying, "Thanks for the update. So I
- 12 can update Ken as to costs, where are we so far? An
- 13 estimate is fine."
- 14 Do you see that?
- 15 A. Yes, I see it.
- 16 Q. Do you recall who Ken is in this e-mail?
- 17 Is that Ken Wittenberg or Ken Stiles or someone
- 18 else?
- 19 A. Huh.
- 20 I don't recall.
- 21 Q. And in the e-mail just above that --
- 22 A. Yes.
- 23 Q. -- Mr. Wendrickx is giving you the cost
- 24 estimate, correct?

- 1 for the auditors with respect to their review of the
- 2 documents?
- 3 A. Only that I saw this in the prep and I
- 4 was the contact person.
- 5 I don't remember other than this if it
- 6 was communicated in another way.
- 7 Q. Do you know if anyone else was ever
- 8 identified by Abbott as being a contact person with
- 9 respect to the audit?
- 10 A. No, I don't know.
- 11 Q. Now, as of June 30th, the date referenced
- in this letter, when Abbott was set to make the
- documents available, do you know how many boxes of
- 14 documents were available?
- 15 A. No, I don't.
- Q. Do you recall how the boxes that were
- 17 made -- let me start again.
- 18 Do you recall whether Abbott made
- 19 documents available on June 30th and that there was
- a visit by the auditors on June 30th?
- A. No, I don't remember.
- Q. Do you recall the first visit by the
- 23 auditors?
- A. I don't remember the date.

- 1 A. I can say that as documents were brought
- 2 to the warehouse -- and I wasn't there every time
- 3 they were brought to the warehouse -- I believe they
- 4 were all put in one location.
- 5 So if RIC documents were collected at one
- 6 time, they would have been put in one spot, if
- 7 outlicensing documents were collected at one time,
- 8 they would have been put in one spot, but I don't
- 9 remember specifics about any organization.
- 10 BY MS. COLLARI TROAKE:
- 11 Q. Did you keep track in any way of the --
- of how many boxes were coming in to the Mundelein
- 13 facility and when those boxes were coming in and
- 14 where they were coming from?
- 15 A. I believe there are e-mails saying
- 16 I'm picking up so many boxes, like the ones you've
- shown, but other than that, I don't believe so.
- 18 Q. So you didn't keep a list or anything of
- 19 which boxes were coming from where and when they
- 20 were delivered to the facility and what might have
- 21 been in them?
- 22 MR. LORENZINI: Objection.
- 23 BY THE WITNESS:
- A. Other than e-mails saying these boxes are

- 1 coming on such-and-such date, like you've already
- 2 shown, I don't believe so.
- 3 BY MS. COLLARI TROAKE:
- 4 Q. Did you have any conversations with the
- 5 folks from StoneTurn during that first visit to the
- 6 Mundelein facility?
- A. I can't remember specifically. I would
- 8 imagine that we said hello, here's your boxes, but I
- 9 don't remember any specifics.
- 10 Q. Do you recall them asking you at any
- 11 point during that first visit when Abbott would have
- 12 the universe of documents referred to in Schedule A
- 13 available for their review?
- 14 A. I recall that question at some point, but
- 15 I don't recall whether I have seen it in documents
- 16 from prep or whether I'm remembering it from a
- 17 conversation with the auditors.
- 18 Q. To the extent that you remember it from a
- 19 conversation with the auditors, do you recall that
- 20 it was asked on more than one occasion, that
- 21 particular question?
- A. I don't know that I remember it from a
- 23 conversation with the auditors, so I don't know how
- 24 often it was asked.

- 1 Q. Do you recall ever giving the auditors an
- 2 answer to that question?
- 3 A. I don't recall if the question was asked,
- 4 so I don't know if I gave them an answer.
- 5 Q. Do you recall ever giving them, whether
- 6 asked or not, a date by which Abbott would complete
- 7 the production of documents called for by
- 8 Schedule A?
- 9 A. I don't recall doing that, no.
- 10 Q. Do you recall around June 30th, 2004,
- 11 telling the copy vendor that Ken had given the okay
- 12 to begin copying again?
- 13 A. No.
- 14 MS. COLLARI TROAKE: 16.
- 15 (WHEREUPON, a document was marked
- 16 Campbell Exhibit No. 16, for
- identification, as of 2/20/07.)
- 18 BY MS. COLLARI TROAKE:
- 19 Q. Ms. Campbell, if I could ask you first --
- 20 there are two documents which are part of
- 21 Exhibit 16.
- 22 A. Yes.
- Q. If you could look at the one that's Bates
- 24 numbered 190542 and 43 first and let me know whether

- 1 MS. COLLARI TROAKE: Yes.
- 2 MR. LORENZINI: -- of the day whether she was
- 3 there for the entire day on the first --
- 4 BY MS. COLLARI TROAKE:
- 5 Q. Let me back up.
- 6 On the first time -- on their first visit
- 7 to the Mundelein facility, were you there the entire
- 8 time they were there, they being the auditors?
- 9 A. I don't remember.
- 10 Q. Do you recall whether anyone else from
- 11 Abbott was at the facility while the auditors were
- there during that first visit at the end of June?
- 13 A. I don't remember.
- 14 Q. Do you recall Mr. Martinez giving you a
- 15 copy of Schedule A during his -- that first visit to
- 16 the Mundelein facility?
- 17 A. It's possible, but I don't specifically
- 18 remember that.
- 19 Q. Do you recall any discussions with
- 20 Mr. Martinez about Schedule A and where in the boxes
- 21 of documents in the warehouse he could find
- 22 particular categories listed on Schedule A?
- A. I don't really remember my conversations
- 24 with him.

- 1 Q. Do you recall telling him at all that you
- 2 didn't know which boxes corresponded to which
- 3 categories on Schedule A, but that you would find
- 4 out and let him know?
- 5 A. I don't remember.
- Q. Do you recall ever providing that
- 7 information to anyone from Stone Turn, that
- 8 information being which documents housed in that
- 9 facility corresponded to which categories on
- 10 Schedule A?
- 11 A. I don't recall --
- 12 THE WITNESS: Oh.
- 13 MR. LORENZINI: You can answer.
- 14 BY THE WITNESS:
- 15 A. I don't recall providing that to anyone.
- 16 BY MS. COLLARI TROAKE:
- 17 Q. Do you recall being asked by Mr. Martinez
- during that first visit when summary level documents
- 19 would be made available by Abbott?
- A. I recall a question like that or similar
- 21 to that, I don't recall specifically, but I don't
- remember when it was asked or if it was
- 23 Mr. Martinez.
- Q. But you recall perhaps someone from

- 1 StoneTurn asking that question?
- 2 A. Yeah. I recall someone -- yes, I recall
- 3 someone, I believe from StoneTurn, asking.
- 4 I might have also seen it in documents.
- Q. Do you recall whether that question was
- 6 asked more than once?
- 7 A. No, I don't remember.
- 8 Q. Do you recall ever providing an answer to
- 9 that question to anyone from StoneTurn?
- 10 MR. LORENZINI: Objection. Vague and
- 11 ambiguous.
- 12 BY THE WITNESS:
- A. No, I don't remember.
- 14 BY MS. COLLARI TROAKE:
- 15 Q. When StoneTurn visited the facility
- during that first visit, did they flag documents to
- 17 be copied or ident -- some other way identify
- 18 documents that they wanted copied?
- 19 A. I believe at some point they did. I
- 20 don't remember if it was during the first visit or
- 21 another visit.
- Q. Okay. Just generally, then, when they
- 23 identified certain documents they wanted to be
- 24 copied, what was your procedure for dealing with

- 1 A. No, I don't remember that.
- 2 Q. You don't recall him saying that things
- 3 were getting moved around and that would slow their
- 4 process because they wouldn't be able to go back and
- 5 find things again?
- 6 A. No, I don't remember that.
- 7 Q. And you don't recall him or anyone else
- 8 from StoneTurn ever making that comment to you prior
- 9 to the December meeting.
- 10 A. No.
- 11 MS. COLLARI TROAKE: 17.
- 12 (WHEREUPON, a document was marked
- 13 Campbell Exhibit No. 17, for
- identification, as of 2/20/07.)
- 15 BY MS. COLLARI TROAKE:
- 16 Q. Ms. Campbell, I've put in front of you
- 17 what's been marked as Exhibit 17. If you could take
- 18 a look at that e-mail string and let me know whether
- 19 you recognize it, please.
- 20 (WHEREUPON, there was a short
- 21 interruption.)
- 22 BY THE WITNESS:
- 23 A. I don't remember it specifically, but I
- 24 have no reason to doubt that it's an e-mail trail

- 1 between Jim and I.
- 2 BY MS. COLLARI TROAKE:
- Q. Looking at the page Bates labeled 126596,
- 4 which is the second page of Exhibit 17, it's an
- e-mail from you, July 7th, to Jim, and it says, "Due
- 6 to the growing size of this project, I will need
- 7 daily updates as to the costs and box counts. A
- 8 quick e-mail will suffice."
- 9 Do you see that?
- 10 A. Yes, I see that.
- 11 Q. Do you recall whether you actually
- 12 received those daily updates from Mr. Wendrickx?
- 13 A. I don't know.
- 14 Q. Do you recall why you requested those
- 15 daily updates?
- 16 A. No.
- 17 Q. Do you recall if you provided the
- information that Mr. Wendrickx provided to you in
- those daily updates to anyone else at Abbott?
- A. I don't know if I got the daily updates
- and I don't know if I provided any updates to
- anyone.
- Q. If you got the updates, would you have
- saved them in your e-mail?

- 1 A. It's possible. I don't know.
- 2 Q. At the top of that same page --
- 3 A. Yes.
- 4 Q. -- Mr. Wendrickx has provided you with
- 5 some information about the status of boxes, and it
- 6 looks like 37 boxes of blow-backs, for example, and
- 7 a total of \$34,350.
- 8 Do you see that?
- 9 A. I see it.
- 10 Q. Do you have any recollection of what you
- 11 did with that update as to where things were in
- 12 early July?
- A. I don't know if I did anything with it.
- Q. And on the first page of Exhibit 17, at
- the top, Mr. Wendrickx says, "Yes, you are probably
- at \$80,000 for the entire project."
- 17 Do you see that?
- 18 A. Yes, I see it.
- 19 Q. Do you have any recollection of receiving
- 20 that information from Mr. Wendrickx in early July?
- A. No. I have no reason to doubt the
- 22 e-mail.
- Q. Do you recall whether you forwarded that
- 24 information to anyone else at Abbott?

- 1 A. No, I don't know.
- 2 Q. Do you recall whether you provided it to
- 3 Mr. Wittenberg?
- 4 A. No, I don't know.
- 5 Q. Or Mr. Stiles?
- 6 A. I don't know.
- 7 Q. Did you ever do any work directly for
- 8 Mr. Stiles?
- 9 A. I don't think so, no.
- 10 MS. COLLARI TROAKE: 18.
- 11 (WHEREUPON, a document was marked
- 12 Campbell Exhibit No. 18, for
- identification, as of 2/20/07.)
- 14 BY MS. COLLARI TROAKE:
- 15 Q. Ms. Campbell, if you could take a look at
- 16 Exhibit 18, please, and let me know whether you
- 17 recognize it.
- 18 (WHEREUPON, there was a short
- 19 interruption.)
- 20 BY THE WITNESS:
- 21 A. Okay.
- 22 BY MS. COLLARI TROAKE:
- Q. Do you recognize it?
- A. Yes, I do.

- 1 Q. Excuse me?
- 2 A. Yes, I do.
- 3 Q. And do you recognize it from sometime
- 4 other than before your meeting with Mr. Lorenzini?
- 5 A. Yes, I do.
- 6 Q. And what is it?
- A. It appears to be a string of e-mails.
- 8 Q. Between you and Mr. Wendrickx, the copy
- 9 vendor?
- 10 A. Yes.
- 11 I should qualify one thing. I recognize
- this e-mail from Jim, 7/13/04.
- 13 Q. Uh-huh.
- 14 A. That's what I recognize.
- Q. Just that one e-mail.
- 16 A. Yes.
- 17 Q. Not the rest.
- 18 A. But I have no reason to doubt this is an
- 19 e-mail string, but that's what I recognize.
- 20 Q. Okay. If we could first go -- go to
- 21 Page 126416, this is actually the e-mail we were
- 22 talking about in Exhibit 17 --
- A. Right.
- 24 Q. -- where you were asking him for the

- 1 updates.
- 2 You also say "...it's hard to do this
- 3 remotely." Do you see that?
- 4 A. I saw it when I read it. Let me find it.
- 5 Q. Just before your signature block there.
- 6 A. Okay. Yeah.
- 7 Q. What did you mean by that?
- 8 A. I'm not certain. I might have been
- 9 traveling.
- 10 Q. Were you working on other projects at the
- 11 same time you were working on the Hancock audit?
- 12 A. Yes.
- 13 Q. Do you recall how many other projects you
- were working on at the same time you were working on
- 15 the Hancock audit?
- 16 A. No.
- 17 Q. Now, on the page numbered 126414 --
- 18 A. Okay.
- 19 Q. -- at the bottom of the page is an e-mail
- 20 from Mr. Wendrickx, July 9th.
- 21 A. I see it.
- 22 Q. All right. And he estimates that the new
- 23 grand total will be around \$100,000.
- 24 Do you see that?

- 1 A. I see that.
- 2 Q. Okay. Do you recall getting that
- 3 information around early July, '04?
- 4 A. I don't recall when. I recall the
- 5 number, 100,000. I'm not sure where I get the
- 6 number. I recall that being a number of costs.
- 7 Q. Do you know why you recall that specific
- 8 number?
- 9 A. No. I think just because it was 100,000.
- 10 I don't know why I remember it.
- 11 Q. And at the top of that page you wrote
- 12 back to Mr. Wendrickx and you told him to hold on
- 13 the 30 boxes for today --
- 14 A. I see that, yes.
- 15 Q. -- and that you needed to talk to Ken on
- 16 Monday.
- 17 A. Yes.
- 18 Q. Is that Ken Wittenberg?
- 19 A. I don't know.
- 20 Q. Were you talking to Ken Stiles on a
- 21 regular basis during the Hancock audit?
- 22 A. I believe I was talking to him
- 23 occasionally. I don't know how often.
- Q. Do you recall providing Mr. Stiles

- 1 regular updates about copying costs in relation to
- 2 the audit?
- 3 A. No, I don't remember.
- 4 Q. Do you recall getting Mr. Wittenberg
- 5 regular updates as to the costs of the copying in
- 6 relation to the audit?
- 7 A. I don't remember getting anybody regular
- 8 updates as to copy costs.
- 9 Q. Do you recall giving Mr. Wittenberg
- 10 regular updates about the progress of the collection
- of documents in relation to the audit?
- 12 A. I recall talking to Ken about the audit.
- 13 I don't know how often and I don't know what we
- 14 talked about specifically.
- 15 Q. So you don't recall speaking to
- Mr. Wittenberg at any time about the costs of the
- 17 copying approaching \$100,000.
- 18 A. I didn't say that.
- 19 I don't recall having regular
- 20 conversations with Ken or providing regular updates
- 21 about copy costs.
- 22 Q. Do you recall having a conversation with
- 23 Mr. Wittenberg about the copying costs related to
- the audit approaching around \$100,000?

- 1 A. I don't know. I don't remember.
- Q. On the first page of Exhibit 18 --
- 3 A. Yeah.
- 4 Q. -- is an e-mail from you to
- 5 Mr. Wendrickx on July 13.
- Just so we are clear here, on the e-mail
- 7 we were looking at before, that's Friday, July 9th,
- 8 okay, where you say you need to talk to Ken on
- 9 Monday, on the top of 126414.
- 10 A. Okay. I see Friday, July 9th.
- 11 Q. That's Friday, July 9th.
- 12 So Monday would be July 12th.
- 13 A. Okay.
- 14 Q. Okay. So on Tuesday, July 13th, you sent
- an e-mail to Jim, and you say, "We are on hold for
- 16 now."
- 17 A. Okay.
- 18 Q. Do you recall sending that e-mail to him?
- A. No, but I have no reason to doubt what's
- 20 written.
- 21 Q. Do you recall what precipitated you
- sending an e-mail to the vendor saying that, "We are
- 23 on hold for now"?
- 24 A. No.

- 1 Q. Do you know whether -- do you recall
- whether you meant that the copying and collection of
- 3 documents by Abbott was on hold?
- 4 A. No, I don't know.
- 5 Q. Do you recall talking to Mr. Wittenberg
- on Monday, July 12th, about the costs for the audit
- 7 reaching around \$100,000?
- 8 A. No, I don't. No.
- 9 MR. LORENZINI: I was going to object. Asked
- 10 and answered.
- 11 But go ahead.
- 12 BY THE WITNESS:
- 13 A. I don't remember.
- 14 THE WITNESS: Sorry.
- 15 MR. LORENZINI: That's okay.
- 16 BY MS. COLLARI TROAKE:
- 17 Q. Do you recall whether Mr. Wittenberg told
- you to stop copying around this time, in July, '04?
- 19 A. No, I don't remember.
- 20 Q. Do you recall that StoneTurn made a
- 21 second visit to the Mundelein facility just after
- 22 the 4th of July in 2004?
- 23 MR. LORENZINI: Objection. Vague and
- 24 ambiguous.

- 1 BY THE WITNESS:
- 2 A. I don't recall the dates.
- 3 BY MS. COLLARI TROAKE:
- 4 Q. You don't recall that they visited the
- 5 Mundelein facility around July 7th and 8th of 2004?
- 6 A. I don't recall the dates.
- 7 Q. Do you recall making arrangements for the
- 8 auditors to review additional documents at another
- 9 facility, called the Northpoint facility, at some
- 10 point in July, 2004?
- 11 A. I don't recall the dates, but they did
- 12 review documents at another facility, and I believe
- 13 Northpoint was the street address.
- 14 Q. Do you recall why they were reviewing
- documents at that facility and why the documents
- weren't all made available in one location?
- 17 A. I'm not certain why they weren't moved to
- 18 Mundelein. I believe they were letting them review
- originals, and the auditors were fine with it, but I
- don't know why they weren't specifically moved to
- 21 Mundelein.
- Q. Do you recall around the same time making
- 23 documents available at another facility, the
- 24 Green Bay facility?

- 1 A. I recall documents being made available
- 2 in another facility. It was Green something.
- 3 Green Bay is probably it. I don't know the name of
- 4 it.
- 5 Q. And, again, do you know -- or, do you
- 6 recall why documents were made available at a third
- 7 facility and not at the Mundelein facility?
- 8 A. I don't know why they weren't moved to
- 9 Mundelein. I just recall going there and looking at
- 10 originals. I'm not certain why they weren't moved
- 11 to Mundelein.
- 12 Q. Do you recall how you determined that
- 13 boxes at those two facilities, Northpoint and
- 14 Green Bay, needed to be made available to the
- 15 auditors?
- 16 A. I don't recall specifically.
- 17 Northpoint, I believe, is the RIC
- 18 facility address, and I think documents were just
- 19 available and they didn't have a problem with
- 20 looking at them there.
- The Green Bay address is an unmanned
- 22 warehouse that I believe the RIC also used, and I
- 23 was told there were documents at that location and
- they could look at them there.

- 1 A. No, I don't remember specifically.
- 2 Q. Do you recall telling the representatives
- 3 from StoneTurn that you would pass that question
- 4 along and get them an answer?
- 5 A. It's possible, but I don't remember it.
- 6 Q. Do you recall ever providing them an
- 7 answer to that question?
- 8 A. I don't remember ever getting the
- 9 question, so I'm not certain if I provided an
- 10 answer.
- 11 Q. Prior to the December, 2004, meeting at
- 12 the Mundelein facility --
- 13 A. Uh-huh.
- 14 Q. -- with the lawyers and Mr. Martinez were
- 15 you made aware that John Hancock had requested that
- documents be made available in a particular order by
- 17 reference to the categories on Schedule A?
- A. I don't remember if I was made aware.
- 19 I do believe I saw it in documents for
- 20 preparation, something referencing that.
- Q. So do you have any recollection in late
- July or early August, 2004, of John Hancock asking
- 23 Abbott to make the documents available in a
- 24 particular order?

- 1 A. No, I wouldn't necessarily see everything
- 2 John Hancock asked Abbott.
- 3 Q. But if it was in relation to the audit,
- 4 presumably it would have been helpful for you to
- 5 know if the auditors wanted documents in a
- 6 particular order.
- 7 MR. LORENZINI: Objection. Vague and
- 8 ambiguous.
- 9 BY MS. COLLARI TROAKE:
- 10 Q. You can answer.
- 11 A. I--
- 12 MR. LORENZINI: It calls for speculation.
- 13 BY THE WITNESS:
- 14 A. -- don't know if it would have been
- 15 helpful to know anything that the auditors wanted.
- 16 MS. COLLARI TROAKE: 19.
- 17 (WHEREUPON, a document was marked
- 18 Campbell Exhibit No. 19, for
- 19 identification, as of 2/20/07.)
- 20 BY MS. COLLARI TROAKE:
- Q. Ms. Campbell, you've been given
- 22 Exhibit 19. Would you take a look at it, please,
- and let me know whether you recognize it.
- 24 In particular, I'm interested in the

- 1 letter from Choate, Hall & Stewart.
- 2 A. The first -- second page?
- 3 Q. Yes, the second and third pages of the
- 4 exhibit.
- 5 A. Okay.
- 6 (WHEREUPON, there was a short
- 7 interruption.)
- 8 BY MS. COLLARI TROAKE:
- 9 Q. Do you recognize it?
- 10 A. I recognize it from preparation.
- 11 Q. Do you recall seeing that letter in and
- around the end of July of 2004?
- A. I don't recall if I've seen it other than
- 14 in preparation.
- 15 Q. On the second page of the letter there's
- a list of priorities by topic in Schedule A.
- 17 Do you see that?
- 18 A. I see them.
- 19 Q. Do you recall ever having a discussion
- 20 with anyone from Abbott about making available
- 21 documents in this particular order?
- 22 A. No.
- 23 MS. COLLARI TROAKE: 20.
- 24 (WHEREUPON, a document was marked

- 1 Campbell Exhibit No. 20, for
- 2 identification, as of 2/20/07.)
- 3 BY MS. COLLARI TROAKE:
- 4 Q. Ms. Campbell, if you could take a look at
- 5 Exhibit 20 that was just given to you and let me
- 6 know whether you recognize that document, please.
- 7 (WHEREUPON, there was a short
- 8 interruption.)
- 9 BY THE WITNESS:
- 10 A. I've seen this in preparation.
- 11 BY MS. COLLARI TROAKE:
- 12 Q. Do you recall seeing it at any other
- 13 time?
- A. No, I don't recall seeing it.
- 15 Q. On the last page of the letter, which is
- 16 JH 11336, the carryover paragraph -- do you see
- 17 that?
- 18 A. I see it.
- 19 Q. Yeah.
- The last sentence says, "If the documents
- are provided on a rolling basis, we again request
- that they be provided in the following order of
- 23 priority (from highest to lowest priority)," and
- 24 then it gives a list --

- 1 A. I see it, yes.
- Q. -- from Schedule A.
- 3 Do you recall ever seeing that list or
- 4 request for order of priority for the production?
- 5 A. No.
- 6 Q. Do you recall anyone ever discussing with
- 7 you the idea that the documents should be provided
- 8 in a particular order?
- 9 MR. LORENZINI: Objection. Asked and answered.
- 10 BY THE WITNESS:
- 11 A. No, I don't recall.
- 12 BY MS. COLLARI TROAKE:
- 13 Q. Did you keep track of the number of hours
- 14 the representatives from StoneTurn took to review
- the documents made available by Abbott?
- 16 MR. LORENZINI: Objection. Vague and
- 17 ambiguous.
- 18 BY THE WITNESS:
- 19 A. I don't believe I kept track, no, but I'm
- 20 not certain.
- 21 BY MS. COLLARI TROAKE:
- 22 Q. At any point were you asked to try to
- 23 figure out how many hours they had spent?
- A. I don't recall it. I've seen a letter in

- 1 book by the door. I don't know if anybody actually
- 2 signed in and out.
- 3 Q. So do you have any idea how that number,
- 4 95 hours --
- 5 A. I--
- 6 Q. -- came up?
- 7 A. Sorry.
- 8 Q. How that was calculated?
- 9 A. No, I really don't. I only remember
- 10 seeing it in this stuff, documents.
- 11 MS. COLLARI TROAKE: 21.
- 12 (WHEREUPON, a document was marked
- 13 Campbell Exhibit No. 21, for
- identification, as of 2/20/07.)
- 15 BY MS. COLLARI TROAKE:
- 16 Q. Ms. Campbell, do you recognize
- 17 Exhibit 21?
- 18 A. I need to look at it real quick.
- 19 (WHEREUPON, there was a short
- 20 interruption.)
- 21 BY THE WITNESS:
- A. I've seen this in preparation.
- 23 BY MS. COLLARI TROAKE:
- Q. Do you recall seeing it before?

- 1 A. No, I don't recall seeing it.
- Q. On Page 2 of the letter, the paragraph
- 3 beginning "Within approximately 90 days" -- do you
- 4 see that?
- 5 A. I see it, yes.
- 6 Q. There is a reference to 750 boxes.
- 7 A. I see it.
- 8 Q. Do you recall whether that number is
- 9 about right for what had been made available by
- Abbott as of August 5th, 2004?
- 11 A. I don't remember specifically. I have no
- reason to doubt the information in the letter.
- Q. Did you keep track of the number of boxes
- in any way during the course of the audit?
- 15 MR. LORENZINI: Objection. Vague and
- 16 ambiguous.
- 17 You can answer.
- 18 BY THE WITNESS:
- 19 A. I'm thinking.
- 20 I don't recall specifically keeping track
- 21 other than e-mails, you know, we've got 20 boxes
- 22 going here and there, but I didn't -- I don't recall
- 23 tracking them in any way.
- 24 BY MS. COLLARI TROAKE:

- 1 Q. Uh-huh.
- 2 At the top of Page 3, the paragraph
- 3 beginning, "Third, your unexplained statement that
- 4 Hancock understands that the 'majority' of the
- 5 documents made available to date relate to
- 6 Topic 3 of Schedule A -- which requests records
- 7 concerning Abbott's obligations under Section 4.3 of
- 8 the agreement, including replacement compounds,
- 9 outlicensing and divestiture -- is not consistent
- 10 with Abbott's understanding," do you see that?
- 11 A. I see it.
- 12 Q. Do you have any recollection of having an
- 13 understanding about what documents related to which
- topics on Schedule A back in August of '04?
- 15 MR. LORENZINI: Objection. Vague and
- 16 ambiguous.
- 17 BY THE WITNESS:
- 18 A. I don't recall specifically
- 19 cross-referencing documents to the schedule.
- The initial boxes I believe were the RIC
- 21 documents, and I don't believe that would be
- 22 outlicensing and divestiture information.
- 23 BY MS. COLLARI TROAKE:
- Q. Do you recall what percentage of the

- 1 750-some-odd boxes that had been made available at
- this point in time were from the RIC facility?
- 3 A. I don't recall. No, I don't.
- 4 The -- I believe the largest number of
- 5 boxes overall was from the RIC facility, but I don't
- 6 recall the numbers.
- 7 Q. And what type of documents would have
- 8 been from the RIC facility?
- 9 A. I believe it's outlined a little better
- in the 30(b)(6) response, but regulatory filings,
- 11 underlying clinical documents, investigator
- 12 information, expenditures.
- 13 I'm trying to remember.
- That's all I can think of off the top of
- my head. I'm certain there's more information.
- 16 Q. Would those documents have included
- 17 documents as identified in Topic 1 of Schedule A --
- if you want to flip back to Schedule A, that's
- 19 fine -- accounting type documents?
- Exhibit 2.
- A. Okay. I have got them out of order.
- MR. LORENZINI: I'm going to object to your
- 23 characteri -- characterization of Topic 1 as
- 24 strictly accounting-related documents and also

- 1 object based on lack of foundation.
- 2 BY THE WITNESS:
- 3 A. Can -- I'm sorry. Can you state the
- 4 question again?
- 5 MS. COLLARI TROAKE: Could you read it back,
- 6 please.
- 7 (WHEREUPON, the record was read
- 8 by the reporter as requested.)
- 9 BY THE WITNESS:
- 10 A. Again, I'm not certain what accounting
- 11 type documents are.
- 12 I believe there were expenditures, I
- 13 believe there was information -- timesheets from
- 14 corporate records were included, but I didn't look
- through every document, and I don't know every
- 16 document that the RIC maintains.
- 17 BY MS. COLLARI TROAKE:
- 18 Q. So you don't know whether that would have
- 19 included Abbott's chart of accounts?
- A. I don't know.
- 21 Q. Or 1-C, summary of costs/expenditures
- 22 incurred by program compound by year?
- A. I don't know.
- 24 MR. LORENZINI: Objection. Vague and

- 1 Q. 1-H?
- 2 A. I don't know.
- 3 Q. 1-I?
- 4 A. I don't know.
- 5 Q. 1-J?
- 6 A. I don't know.
- 7 Q. 1-K?
- 8 A. I don't know.
- 9 Q. And with respect to 1-L you said there
- 10 were timesheets and some payroll records, is that
- 11 right?
- 12 A. I don't know about payroll records.
- 13 There were timesheets in the corporate records
- 14 boxes.
- 15 Q. Okay. Going back to the August 5th
- 16 letter, so 21 --
- 17 A. Okay.
- 18 Q. -- that same page, Page 3, the last
- 19 sentence in the paragraph that begins with "Fourth"
- 20 says, "Having been forced by Hancock for months to
- 21 gather huge volumes of records indiscriminately,
- 22 Abbott will continue to produce the records in the
- 23 order they are gathered."
- Do you recall whether there was a

- 1 particular order in which you were gathering the
- 2 documents?
- 3 A. No.
- 4 Q. Was there any order of priority that
- 5 determined which documents you gathered first?
- 6 A. No, not that I remember.
- 7 MR. LORENZINI: Do you want to take a break
- 8 anytime soon?
- 9 THE WITNESS: In a few minutes.
- 10 MS. COLLARI TROAKE: 22.
- 11 (WHEREUPON, a document was marked
- 12 Campbell Exhibit No. 22, for
- identification, as of 2/20/07.)
- 14 BY MS. COLLARI TROAKE:
- 15 Q. Do you recognize Exhibit 22?
- 16 A. I don't recognize it, but I have no
- 17 reason to doubt that it's an e-mail trail between
- 18 Jim and I -- or, an e-mail from Jim to me.
- 19 Q. Do you recall requesting from
- 20 Mr. Wendrickx to provide this summary that appears
- 21 on the second page of Exhibit 22?
- A. No, I don't remember it specifically.
- Q. Do you recall what you did with this
- 24 summary when you received it?

- 1 BY THE WITNESS:
- 2 A. I don't know. It's -- the date is
- 3 familiar, but I'm not certain where or why.
- 4 BY MS. COLLARI TROAKE:
- 5 Q. In the next sentence is a reference to
- 6 something -- "desk files of individual Abbott
- 7 employees."
- 8 Do you see that?
- 9 A. I see it.
- 10 Q. Do you have any recollection of what that
- 11 might be referring to?
- 12 MR. LORENZINI: The term "desk files"?
- MS. COLLARI TROAKE: Uh-huh.
- 14 BY THE WITNESS:
- 15 A. I assume they mean a person's files that
- they keep at their desk.
- 17 BY MS. COLLARI TROAKE:
- 18 Q. Did you ever collect documents from
- 19 Abbott employees in relation to the audit that would
- 20 be documents that they kept at their desk?
- A. From the outlicensing people?
- Q. You did or did not?
- A. Yes, the outlicensing people.
- Q. You did.

- 1 Anyone else other than the outlicensing
- 2 people?
- 3 A. I believe Dr. Bukofzer, but I'm not
- 4 certain. I believe so.
- 5 Other than that, I don't remember.
- Q. Do you have any recollection as to why
- 7 those individuals and not others were asked to
- 8 provide their desk files?
- 9 MR. LORENZINI: Objection on the grounds it
- 10 potentially calls for attorney-client privilege and
- 11 work product.
- 12 Please exclude from your answer any --
- any communications with counsel on the subject of
- the scope of document production required by the
- 15 agreement.
- 16 BY THE WITNESS:
- 17 A. No.
- 18 BY MS. COLLARI TROAKE:
- 19 Q. Did someone tell you not to ask anyone
- 20 other than those people for their desk files?
- 21 MR. LORENZINI: Objection. Vague and ambiguous
- 22 and potentially calls for disclosure of
- 23 attorney-client communication.
- 24 MS. COLLARI TROAKE: It's asking did someone.

- 1 It's a yes or no question.
- 2 MR. LORENZINI: Did someone --
- 3 MS. COLLARI TROAKE: Ask her not to collect
- 4 other people's desk files.
- 5 MR. LORENZINI: You can answer yes or no.
- 6 BY THE WITNESS:
- 7 A. I'm not certain. I don't believe so, but
- 8 I'm not certain.
- 9 BY MS. COLLARI TROAKE:
- 10 Q. Do you have any recollection as to why
- 11 you didn't ask for others' desk files?
- 12 A. I'm not certain why.
- 13 Q. Is there any document you could look at
- that might refresh your recollection as to why you
- requested some desk files, but not others?
- A. I can't think of any, but I'm not
- 17 certain.
- 18 Q. If you look at the second page of the
- 19 letter, there's a reference again in that last
- 20 paragraph to 750 boxes and copying costs exceeding
- 21 \$100,000.
- Do you see that?
- A. I see the references.
- Q. And you recall those are the same numbers

- 1 your practice?
- 2 MR. LORENZINI: Objection. Vague and
- 3 ambiguous. Incomplete hypothetical.
- 4 BY THE WITNESS:
- 5 A. It's possible, but I'm not certain.
- 6 BY MS. COLLARI TROAKE:
- 7 Q. Now, we've mentioned a couple of times
- 8 this December meeting at the Mundelein facility.
- 9 A. Yes.
- 10 Q. And you participated in that meeting?
- 11 A. I attended.
- 12 Q. You did.
- Do you recall that meeting originally was
- 14 scheduled for a different day?
- 15 A. I recall it from a document I saw in the
- 16 preparation.
- 17 Q. You don't have an independent
- 18 recollection of it being rescheduled --
- 19 A. No.
- 20 Q. -- or the reasons why?
- 21 A. No.
- 22 Q. Do you recall being out sick for a period
- 23 of time in December of '04?
- A. No, but I did see it in a document in the

- 1 privilege and work product.
- 2 BY MS. COLLARI TROAKE:
- 3 Q. Did the communication with counsel
- 4 include seeking legal advice or obtaining legal
- 5 advice --
- 6 MR. LORENZINI: Objection.
- 7 BY MS. COLLARI TROAKE:
- 8 Q. -- about the redactions?
- 9 MR. LORENZINI: Objection. It calls for a
- 10 legal conclusion.
- 11 You don't -- you don't need to answer.
- 12 THE WITNESS: Oh, okay.
- MR. LORENZINI: It calls for a legal opinion.
- 14 BY MS. COLLARI TROAKE:
- 15 Q. Do you recall Mr. Martinez asking about
- the documents that were flagged in July, again,
- during his visit in January, 2005?
- 18 A. I don't recall the visit in January,
- 19 2005. I don't recall specifically requesting
- 20 documents in January, 2005.
- 21 (WHEREUPON, a document was marked
- 22 Campbell Exhibit No. 30, for
- 23 identification, as of 2/20/07.)
- 24 BY MS. COLLARI TROAKE:

- 1 he hadn't received those documents?
- 2 A. I don't remember.
- 3 Q. In the first paragraph Mr. Martinez
- 4 refers to Yolanda.
- 5 Is that Yolanda -- I can't remember her
- 6 last name now -- that you mentioned earlier who is a
- 7 paralegal at Abbott?
- 8 A. I assume it is. It's the only Yolanda I
- 9 know.
- 10 Q. Do you have any -- any reason to think it
- 11 was someone else?
- 12 A. I have no reason to think that, no.
- 13 Q. Do you have any recollection about -- let
- 14 me start again.
- 15 In the last paragraph, beginning
- 16 "Further, as I understand" -- do you see that --
- there is a reference to completing the production by
- 18 January 31st.
- 19 Do you see that?
- A. I see that there's a reference to
- 21 documents being available on January 31st.
- 22 Q. Well, it says, "...as I understand that
- 23 all of the Abbott documents responsive to
- 24 John Hancock's request for documents will be

- 1 available by January 31, 2005."
- 2 Do you see that?
- 3 A. I see it, yes.
- 4 Q. Do you have any recollection of working
- 5 towards that date as the date for completing the
- 6 production?
- 7 A. I think that's the date I said before
- 8 sounds familiar, but I'm not certain why it's
- 9 familiar.
- 10 I believe that's the date.
- 11 Q. Do you recall meeting Mark Hair from
- 12 StoneTurn at some point during the course of the
- 13 audit?
- 14 A. I believe I met him, but I'm not certain.
- MS. COLLARI TROAKE: This is going to be 31.
- 16 (WHEREUPON, a document was marked
- 17 Campbell Exhibit No. 31, for
- identification, as of 2/20/07.)
- 19 MS. COLLARI TROAKE: And this one is going to
- 20 be 32.
- 21 (WHEREUPON, a document was marked
- 22 Campbell Exhibit No. 32, for
- identification, as of 2/20/07.)
- 24 BY MS. COLLARI TROAKE:

- 1 time-consuming than originally anticipated."
- 2 Do you see that?
- 3 A. I see it.
- 4 Q. Do you recall working overtime in late
- 5 January, 2005, in order to try and make these
- 6 documents available by January 31st?
- 7 A. I don't work overtime. I mean, I
- 8 don't -- overtime is not part of my job. I recall
- 9 working a lot of hours, and I recall working late,
- and I believe it was around this time frame, but I'm
- 11 not certain.
- 12 Q. Do you recall working weekends around
- 13 this time frame on the Hancock audit?
- 14 A. Huh.
- 15 I don't recall. I don't recall either
- 16 way.
- 17 Q. Other than the contract attorneys and
- paralegals that we previously talked about, do you
- 19 recall any other personnel that were hired in
- 20 relation to reviewing these documents in January,
- 21 2005?
- 22 A. I don't believe there are any -- I don't
- 23 believe anybody was hired other than the contract
- 24 people.

- 1 sentence says, "You can also bring the boxes you
- 2 have been holding to Mundelein if you have time."
- 3 Do you recall what that's referring to?
- 4 A. No.
- Q. Would you take a look at Exhibit 34 now,
- 6 please.
- 7 Oops. Sorry. There you go.
- 8 And if you could take a look at the
- 9 e-mail string and also the attached document, and
- 10 it's Bates labeled ABBT 175 through 181A, and let me
- 11 know if you recognize that e-mail and the attached
- document, please.
- 13 (WHEREUPON, there was a short
- 14 interruption.)
- 15 BY THE WITNESS:
- A. No, I don't recall this document.
- 17 BY MS. COLLARI TROAKE:
- 18 Q. With respect to the attachment, which
- 19 begins on 1 -- Bates No. 178, which is GPRD Quality
- 20 Assurance Monthly Highlights, December, 2003, do you
- 21 see that?
- A. I see it.
- Q. And you will agree with me that a lot of
- this document appears to be redacted on the

- 1 subsequent pages?
- 2 A. Yes.
- 3 MR. LORENZINI: Objection.
- 4 THE WITNESS: Oh.
- 5 MR. LORENZINI: I don't know if there was
- 6 other -- you know, if this was part of a larger
- 7 document or a stand-alone document.
- 8 BY MS. COLLARI TROAKE:
- 9 Q. Ms. Campbell, on Page 181A, at the
- 10 bottom --
- 11 A. 181A.
- 12 Q. It's the last page of the exhibit.
- 13 A. Okay. Oh, sorry.
- 14 Okay.
- 15 Q. At the bottom right does it say Page 5 of
- 5 there? 16
- 17 It says Page 5 of 5.
- 18 Q. Thank you.
- 19 Do you recall anyone discussing with you
- 20 this particular document and the level of redaction
- 21 to this document?
- 22 MR. LORENZINI: Objection.
- 23 If you could exclude from your answer
- 24 anything -- any communications with counsel on the

- 1 subject of redaction of this document. Otherwise,
- 2 you can answer.
- 3 BY THE WITNESS:
- 4 A. I don't remember this document at all.
- 5 BY MS. COLLARI TROAKE:
- 6 Q. You don't remember discussing it with
- 7 anyone?
- 8 A. No.
- 9 Q. Were you ever made aware that certain
- documents that were redacted in the course of the
- 11 audit -- this particular document being one
- 12 example -- were later produced in the litigation in
- 13 unredacted form?
- 14 A. Yes, I was -- I believe I was made aware
- 15 that certain documents were produced in unredacted
- 16 form later, in the second case.
- 17 Q. Do you have any knowledge as to why
- 18 they're -- they were redacted in the course of the
- audit, but then later produced in the litigation?
- 20 MR. LORENZINI: Objection. It potentially
- 21 calls for attorney-client communications and work
- 22 product.
- 23 BY THE WITNESS:
- 24 A. I don't know.

- 1 StoneTurn?
- A. I don't recall the visit. I don't recall
- 3 the number of boxes.
- 4 Q. Do you recall being present at the
- 5 Mundelein facility for any of those days at the
- 6 beginning of March, when the StoneTurn auditors were
- 7 there?
- 8 A. It's possible, but I don't remember.
- 9 Q. Do you recall whether anyone else on
- 10 behalf of Abbott was present at the Mundelein
- 11 facility during those days in March?
- 12 A. I don't believe they would have been at
- the warehouse without somebody present, but I don't
- 14 specifically -- without somebody representing Abbott
- 15 present, but I don't specifically recall.
- 16 Q. So you don't recall meeting Mark Hair
- 17 from StoneTurn during that week at the Mundelein
- 18 facility?
- 19 A. I think I said before that I recall
- 20 meeting him at some point. That may have been the
- 21 week, but I don't specifically remember it.
- 22 MS. COLLARI TROAKE: 36.
- 23 (WHEREUPON, a document was marked
- 24 Campbell Exhibit No. 36, for

- 1 identification, as of 2/20/07.)
- 2 BY MS. COLLARI TROAKE:
- 3 Q. If you could take a look at Exhibit 36,
- 4 please, and let me know whether you recognize that
- 5 document.
- 6 A. I recognize this from the preparation
- 7 session.
- 8 Q. Do you recognize it from before the
- 9 preparation?
- 10 Any recollection of getting it at or
- around the date it's dated, March 10th, '05?
- 12 A. No specific recollection, but I have no
- 13 reason to doubt that I got it if it's directed to
- 14 me.
- 15 Q. In the first sentence -- well, it's an
- 16 e-mail from Mark Hair to you, correct?
- 17 A. Well, it doesn't look like a normal
- 18 e-mail printed, but it seems to be an e-mail from
- 19 Mark Hair to me.
- Q. And in the first sentence it says, "It
- 21 was good to meet you briefly yesterday at
- 22 Mundelein."
- 23 Does that refresh your recollection at
- all as to when you met Mark Hair and that you were

- 1 at the facility at least on March 9th?
- A. I have no reason to doubt that I met him
- on that day, but it doesn't refresh my memory.
- 4 Q. Do you recall having any discussions with
- 5 Mr. Hair about the documents that were being made
- 6 available by Abbott?
- 7 A. I don't really recall meeting him, so I
- 8 don't recall having discussions, but, again, I
- 9 assume I received this e-mail.
- 10 Q. Do you recall any discussions about the
- 11 fact that there were very few, if any, e-mails
- 12 provided in the documents that were made available
- by Abbott in the course of the audit?
- A. I saw this in a doc -- in the review.
- 15 That's the only recollection I have of that.
- 16 Q. Aside from what's in this particular
- 17 e-mail, do you have any recollection about
- 18 collecting and making available e-mails in the
- 19 course of the audit, other than I think you said
- 20 that Mr. Pinto provided some e-mails?
- 21 A. I believe it was Mr. Mickel.
- 22 Q. Mr. Mickel.
- A. No, I don't remember specifically
- 24 discussing e-mails.

- 1 Q. Do you recall making any particular
- 2 requests to any of the individuals that you were
- 3 speaking with about collecting and providing
- 4 documents that they provide e-mails in relation to
- 5 the audit?
- 6 A. I don't remember specifically, but I
- 7 believe that the outlicensing people were asked to
- 8 provide any e-mails that they had.
- 9 Q. Other than the outlicensing people, was
- 10 anyone else asked to provide e-mails?
- 11 A. Not that I recall, but I'm not certain.
- 12 Q. Did the outlicensing people, in fact,
- 13 provide e-mails?
- 14 A. The one I specifically remember is Steve
- 15 Mickel, but I'm not certain about the others.
- 16 Q. So you don't recall one way or the other.
- 17 A. I recall Steve Mickel. The other ones I
- 18 don't.
- 19 Q. Other than him.
- A. No, I don't recall.
- 21 Q. Is there any document that you could look
- 22 at that would refresh your recollection about
- 23 whether you received e-mails from other people other
- than Mr. Mickel in the outlicensing group?

- 1 A. I don't remember it specifically.
- 2 Q. Do you recall when that was?
- 3 A. No. I don't remember the date.
- 4 Q. At the end of Mr. Hair's e-mail he talks
- 5 about getting information about how the documents
- 6 provided relate to the documents requested on
- 7 Schedule A.
- 8 Do you see that bit of his e-mail, the
- 9 last paragraph?
- 10 A. Yeah, I'm just looking at it.
- 11 I see that, yes.
- 12 Q. And he has attached a spreadsheet.
- 13 A. Yes, I see that.
- 14 Q. Do you see that?
- 15 A. Yeah, I see that.
- 16 Q. Do you recall ever responding to that
- 17 particular request by Mr. Hair?
- 18 A. I don't believe so, but I'm not certain.
- 19 Q. Do you recall ever providing the
- 20 information he is requesting in that last paragraph
- and in the attachment at any time after March 10,
- 22 <mark>2005?</mark>
- 23 MR. LORENZINI: Objection. Vague and
- 24 ambiguous.

- 1 BY THE WITNESS:
- 2 A. I don't recall.
- 3 BY MS. COLLARI TROAKE:
- 4 Q. Do you know if anyone else at Abbott
- 5 provided that information?
- 6 A. I -- I don't believe so, but I wouldn't
- 7 know for certain.
- 8 Q. Other than you, do you know if anyone
- 9 else would have been -- would have been able to
- 10 provide that information?
- 11 MR. LORENZINI: Objection. Vague and
- 12 ambiguous. It calls for speculation.
- 13 BY THE WITNESS:
- 14 A. I don't know if they would have been able
- 15 to.
- 16 BY MS. COLLARI TROAKE:
- 17 Q. Do you recall whether you would have been
- able to provide the information at that time that
- 19 was requested by Mr. Hair in that last paragraph and
- in the attachment?
- 21 A. Do I recall if I would have been able
- 22 to --
- 23 Q. Uh-huh.
- A. -- provide the information?

- 1 at Abbott.
- 2 Q. Do you recall forwarding the request
- along to Mr. Wittenberg and Mr. D'Amore?
- 4 A. I don't recall doing it, no.
- 5 Q. Just give me a minute.
- 6 (WHEREUPON, there was a short
- 7 interruption.)
- 8 MS. COLLARI TROAKE: This is going to be 37.
- 9 (WHEREUPON, a document was marked
- 10 Campbell Exhibit No. 37, for
- identification, as of 2/20/07.)
- 12 BY MS. COLLARI TROAKE:
- 13 Q. Ms. Campbell, if you would take a look at
- 14 Exhibit 37, please, and let me know whether you
- 15 recognize that document.
- 16 A. Yes, I do recognize this from the
- 17 preparation.
- 18 Q. Do you have any recollection of it other
- 19 than having seen it yesterday, during your
- 20 preparation?
- A. No, but I have no reason to doubt that
- 22 it's my e-mail to Mark Hair.
- Q. In this e-mail you say you are responding
- 24 to the March 10th e-mail, which is Exhibit 36, is

- 1 MS. COLLARI TROAKE: No.
- 2 I think under the rules it's a speaking
- 3 objection.
- 4 MR. LORENZINI: Well, I'm not sure it's --
- 5 MS. COLLARI TROAKE: Just say objection.
- 6 MR. LORENZINI: I don't think that's true.
- 7 I also think it may be helpful to you to
- 8 re -- to clarify your question for me to explain the
- 9 basis for the objection. If you want to fix the
- 10 question, I think it could be helpful to you.
- 11 BY MS. COLLARI TROAKE:
- 12 Q. Did you understand the question?
- 13 A. Could you say it again or read it back?
- 14 Q. Prior to sending this e-mail on
- March 22nd, did you undertake any analysis to
- 16 determine whether Abbott had made available or
- 17 produced the documents referred to in the list that
- was provided at the December, 2004, meeting?
- 19 MR. LORENZINI: Objection. Vague. Ambiguous.
- 20 BY THE WITNESS:
- 21 A. I don't remember if I -- if I did
- 22 anything -- made any analysis pertaining to the
- 23 list. I don't remember.
- 24 BY MS. COLLARI TROAKE:

- 1 Q. Did you go through the list item by item
- 2 and determine whether Abbott had made documents
- 3 available with respect to each category on that
- 4 list?
- 5 A. I don't remember.
- Q. Do you know if anyone else at Abbott
- 7 undertook that task?
- 8 A. I don't know.
- 9 Q. Do you know -- do you recall whether you
- 10 went through Schedule A that was originally provided
- 11 by John Hancock to determine whether documents
- 12 responsive to each category in Schedule A had been
- made available by Abbott prior to sending this
- 14 e-mail on March 22nd?
- MR. LORENZINI: Objection. Asked and answered.
- 16 BY THE WITNESS:
- 17 A. I don't remember.
- 18 BY MS. COLLARI TROAKE:
- 19 Q. Do you know if anyone else undertook that
- 20 task at Abbott?
- 21 MR. LORENZINI: Objection. Vague and
- 22 ambiguous.
- 23 BY THE WITNESS:
- A. I don't know.

- 1 BY MS. COLLARI TROAKE:
- 2 Q. What was the basis for your statement
- 3 that "Abbott has fulfilled its obligation to comply
- 4 with the audit provision of the contract"?
- 5 MR. LORENZINI: Objection.
- 6 Yeah.
- 7 Could we take just a short break to
- 8 confer regarding an issue of whether this would
- 9 require disclosure of attorney-client privilege?
- 10 MS. COLLARI TROAKE: Yeah. If you think you
- 11 need to to address that issue, yes.
- 12 MR. LORENZINI: Okay.
- 13 THE VIDEOGRAPHER: We are going off the video
- 14 record at 4:46 p.m.
- 15 This concludes Tape No. 5.
- 16 (WHEREUPON, a recess was had.)
- 17 THE VIDEOGRAPHER: Okay. We are going back on
- the video record at 4:50 p.m.
- This is the beginning of Tape No. 6.
- 20 MS. COLLARI TROAKE: Could you read back the
- 21 last question, please.
- 22 (WHEREUPON, the record was read
- by the reporter as requested.)
- 24 BY THE WITNESS:

- 1 A. That was the conclusion of the attorneys.
- 2 BY MS. COLLARI TROAKE:
- Q. At that point, March 22nd, 2005, had --
- 4 was StoneTurn -- let me start again.
- As of March 22nd, 2005, do you recall
- 6 whether StoneTurn had been able to speak to anyone
- 7 at Abbott regarding the documents that had been made
- 8 available other than you and the other paralegals or
- 9 contract attorneys and paralegals?
- 10 A. I don't know.
- 11 Q. Did you ever make any arrangements on
- 12 their behalf for them to speak to someone at Abbott
- other than paralegals and attorneys to discuss the
- 14 documents that they were reviewing?
- 15 A. I don't recall ever making such
- 16 arrangements.
- 17 Q. Do you know if anyone else at Abbott ever
- made such arrangements?
- 19 A. I have no way of knowing that.
- Q. Can you take a look back at Exhibit 29,
- 21 please --
- 22 A. Sure.
- 23 Q. -- which is the list from the December
- 24 meeting.

- 1 to No. 21.
- 2 A. I believe these documents were collected
- and produced from Rich Pinto, but I don't
- 4 specifically recall -- recall as an answer to your
- 5 question.
- 6 Q. 22?
- 7 A. I don't recall.
- 8 Q. 23?
- 9 A. I never found anybody who knew what
- 10 Abbott's knowledge management system was, and I
- 11 don't recall specific to your question.
- 12 Q. Prior to sending the March 22nd e-mail,
- did you confirm that Abbott had made available its
- chart of accounts to the auditors?
- 15 MR. LORENZINI: Objection. Vague and
- 16 ambiguous.
- 17 BY THE WITNESS:
- A. I'm not sure what a chart of accounts is.
- 19 We made available financial documents.
- 20 BY MS. COLLARI TROAKE:
- Q. So you don't know what a chart of
- 22 accounts is.
- 23 A. No.
- Q. Did you -- if you go back to Schedule A,

- 1 which is attached to Exhibit 2 --
- 2 A. Exhibit 2.
- 3 Okay.
- 4 Q. On Schedule A, Item 1-B, it says Abbott's
- 5 chart of accounts.
- 6 Do you see that?
- 7 A. I see it.
- 8 Q. Do you recall asking anyone either at
- 9 Abbott or the StoneTurn auditors what was meant by
- 10 chart of accounts as referred to in Schedule A?
- 11 A. I don't believe I asked that of StoneTurn
- 12 and I don't recall if I asked that of Abbott people.
- Q. Prior to sending the March 22nd e-mail,
- 14 did you confirm that Abbott had made available
- documents that are called for by Schedule A in
- 16 Exhibit 2?
- 17 MR. LORENZINI: Objection. Vague and
- 18 ambiguous.
- 19 BY THE WITNESS:
- A. Documents were made available, but I did
- 21 not -- I don't recall if I confirmed prior to this
- 22 e-mail.
- 23 BY MS. COLLARI TROAKE:
- 24 Q. Did you confirm that documents were

- 1 Q. The people that you contacted within
- 2 Abbott to collect documents from, did you ever
- 3 provide those individuals with a copy of Schedule A
- 4 in Exhibit 2?
- 5 A. I don't know.
- 6 Q. So you might have, you might not have;
- 7 you don't know?
- 8 A. Yeah, I really don't know.
- 9 Q. What information did you provide to the
- 10 individuals that you were speaking with about
- 11 collecting documents at Abbott regarding the audit?
- 12 MR. LORENZINI: Objection. Vague.
- 13 You can answer.
- 14 BY THE WITNESS:
- 15 A. I don't recall specifically. I might
- have said that there's an audit, but I don't
- 17 remember anything other than that. I don't remember
- 18 discussing the audit.
- 19 BY MS. COLLARI TROAKE:
- 20 Q. Do you remember reviewing with any of
- 21 them the particulars of Schedule A?
- MR. LORENZINI: Excuse me.
- 23 The --
- 24 MS. COLLARI TROAKE: The particulars of

	Page 315	
1	IN THE UNITED STATES DISTRICT COURT	
2	FOR THE DISTRICT OF MASSACHUSETTS	
3		
4	JOHN HANCOCK LIFE INSURANCE )	
5	COMPANY, et al.,	
6	Plaintiffs, ) Civil Action	
7	vs. ) No. 05-11150-DPW	
8	ABBOTT LABORATORIES, )	
9	Defendant. )	
10		
11	I hereby certify that I have read the	
12	foregoing transcript of my deposition given at the	
13	time and place aforesaid, consisting of Pages 1 to	
14	314, inclusive, and I do again subscribe and make	
15	oath that the same is a true, correct and complete	
16	transcript of my deposition so given as aforesaid,	
17	and includes changes, if any, so made by me.	
18	hill file	
19	MICHELLE CAMPBELL	
20	SUBSCRIBED AND SWORN TO	
21	before me this // لل day	
22	of April , A.D. 2007.	
23	MoSS	
24	Notary Public	
	"OFFICIAL SEAL"  MONA LISA S. FISHER  NOTARY PUBLIC, STATE OF ILLINOIS MY COMMISSION FXPIRES 6/9/2007	

## ERRATA SHEET

## CORRECTIONS:

Page Line	Now Reads	Should Read
13 5	Surzinski	SOCZUNSKI
ale 13	Surzinski	Serzyuski
27 20	SURZINSKI	Serzynsky
38 19	Surzinski	Serzynski
60 12	wasn't the Initial	was the Initial
85 Le	Michele	michelle
88 18	bowalock	Rowaltk
95 15	Booh!	Boo 11
102 53	Michele	Michelle
73 39	Wheeling Chica	up Wheeling
1910 19	Surzinski	- Serzyuski
13316	Ballock I see these	Believe I have soen these
246 I	bowaloch	Kowaluk

Signature of Deponent

# **Deposition Exhibit 1** P's Exhibit 32 PART 1

i [

#### RESEARCH FUNDING AGREEMENT

by and between

#### ABBOTT LABORATORIES

and

JOHN HANCOCK LIFE INSURANCE COMPANY, JOHN HANCOCK VARIABLE LIFE INSURANCE COMPANY,

and

INVESTORS PARTNER LIFE INSURANCE COMPANY

dated as of

March 13, 2001

Campbell 1. 2/20/07 45

ţ,

### TABLE OF CONTENTS

ARTICLE I - DEFINITIONS1			
ART	TCLE 2 - ANNUAL RESEARCH PROGRAM	9	
2.1			
2.2			
2.3		10	
2.4			
2.5		10	
	ICLE 3 - RESEARCH FUNDING		
3.1			
3.2		11	
3.3		11	
3.4		12	
3.5	Hancock Funding Obligation	13	
	ICLE 4 - PRODUCT RESEARCH AND DEVELOPMENT		
4.1	Commercially Reasonable Efforts	13	
4.2	Marketing and Sale Responsibility		
4.3	Failure of Program Compound to Progress		
4.4	Arm's-Length	16	
4.5	In-License Agreements.	16	
ARTI	CLE 5 - PROGRAM INVENTIONS	17	
5.1	Ownership.	17	
5.2	Patent Prosecution and Maintenance	17	
5.3	<u>Enforcement</u> .	17	
ARTI(	CLE 6 - MILESTONE PAYMENTS TO JOHN HANCOCK	17	
6.1	[Intentionally omitted]	17	
6.2	Management Fee	17	
6.3	Milestone Notification and Payments	18	
ARTIC	CLE 7 - ROYALTIES	19	
7.1	Rovalty Rates	19	
7.2	Rovalty Term	19	
AK HC	LE 8 - ROYALTY REPORTS AND ACCOUNTING	20	
8.1 8.2	Reports, Exchange Rates	20	
8.2 8.3	Audits	20	
	Confidential Financial Information	21	
8.4	Accounting Principles.	21	
AKIIC	LE 9 - PAYMENTS	22	
9.1	Payment Terms	22	
9.2	Payment Method CONFIDENTIAL	22	
9.3	Late Payments	22	
LRTICI	LE 10 - CONFIDENTIALITY JA 0080/9	22	

ĺ

1

Book Wall than

10.1	Nondisclosure Obligations	22
10.2	Permitted Disclosures	22
10.3	Publicity Review	
ARTIC	LE 11- TERM AND TERMINATION	23
11.1	Expiration	23
11.2	Termination; Material Breach	
11.3	Effect of Expiration of Termination	
ARTIC	E 12 - WARRANTIES AND INDEMNITY	24
12.1	John Hancock Representations and Warranties	
12.2	Abbott Representations and Warranties	
12.3	No Conflict	
12.4	Compliance with Law	
12.5	No Other Warranties	
12.6	Indemnification of John Hancock	
12.7	Indemnification of John Hancock Relating to In-Licensed Compounds	30
12.8	Procedure	
12.9	Insurance	
12.10	Acknowledgment	
ARTICL	E 13 - FORCE MAJEURE	31
ARTICL	E 14 - ASSIGNMENT	31
ARTICL	E 15 - SEVERABILITY	37
ARTICL	E 16 - MISCELLANEOUS	37
16:1	Notices Applicable Law Entire Agreement	ີ່ເງົ້າ
16.2	Applicable Law	34
16.3	Entire Agreement	34
16.4	Headings.	34
16.5	Independent Contractors	34
16.6	Performance By Affiliates	35
16.7	Dispute Resolution	35
16.8	Waiver	35
16.9	Counterparts	35
		**************************************
EXHIBIT 1.	The state of the s	
EXHIBIT 1.		
EXHIBIT 1.40: Program Compounds		
EXHIBIT I.	The state of the s	
EXHIBIT 9.		
EXHIBIT 12 EXHIBIT 12		
EXHIBIT 12		
شلتا كالمستنفظة	-(v). Communications	

CONFIDENTIAL JH 008080

EXHIBIT 12.2(i):

Compound Reports

(

I

#### RESEARCH FUNDING AGREEMENT

This Research Funding Agreement is made as of March 13, 2001, by and between Abbott Laboratories; an Illinois corporation ("Abbott"), with its principal offices at 100 Abbott Park Road, Abbott Park, Illinois 60064-6049, and John Hancock Life Insurance Company, a Massachusetts corporation, John Hancock Variable Life Insurance Company, a Massachusetts corporation, and Investors Partner Life Insurance Company, a Delaware corporation (collectively, "John Hancock"), each with its principal offices at 200 Clarendon Street, Boston, Massachusetts 02117.

#### WITNESSETH

WHEREAS, Abbott is a global healthcare company actively engaged in the research and development of human pharmaceutical products;

WHEREAS, Abbott is interested in obtaining additional funding to support such research and development activities with respect to certain pharmaceutical products which are under development; and

WHEREAS, John Hancock is interested in providing such additional funding in exchange for the right to receive future milestone and royalty payments from Abbott.

way go na managa na wa a

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and undertakings contained herein, the parties hereto agree as follows:

#### ARTICLE I **DEFINITIONS**

In addition to the other terms defined elsewhere herein, the following terms shall have the following meanings when used in this Agreement (and any term defined in the singular shall have the same meaning when used in the plural and vice versa, unless stated otherwise):

- "Affiliate" shall mean, with respect to each party, any corporation or other form 1.1 of business organization, which directly or indirectly owns, controls, is controlled by, or is under common control with, such party. An entity shall be regarded as being in control of another entity if the former entity has the direct or indirect power to order or cause the direction of the policies of the other entity whether (i) through the ownership of more than fifty percent (50%) in the United States, or thirty percent (30%) or more outside the United States, of the outstanding voting securities (or other ownership interest for a business organization other than a corporation) of that entity; or (ii) by contract, statute, regulation or otherwise.
  - "Aggregate Carryover Amount" shall have the meaning given in Section 3.3. 1.2

M:\Domestic\Pals & Adams\Uohn Hancock\UH rfa FINAL\_DOC

Last printed 3/13/01 1:47 PM

Į

- 1.3 "Aggregate Spending Target" shall mean Six Hundred Fourteen Million Dollars (\$614,000,000).
  - 1.4 "Annual Carryover Amount" shall have the meaning given in Section 3.3.
- 1.5 "Annual Minimum Spending Target" for each Program Year, shall mean the sum of (i) the Program Payment of John Hancock for such Program Year as specified in Section 3.1, (ii) Fifty Million Dollars (\$50,000,000), and (iii) any Annual Carryover Amount for the prior Program Year pursuant to Section 3.3. With respect to the fifth Program Year, the "Annual Minimum Spending Target" shall mean the Annual Carryover Amount for the prior Program Year pursuant to Section 3.3.
- 1.6 "Annual Research Plan" shall mean, for the Program Years in the Program Term, a reasonably and consistently detailed statement of the objectives, activities, timetable and budget for the Research Program for every Program Year remaining in the Program Term, it being understood that less detail shall be required for Program Years that are not the current Program Year. The first Annual Research Plan is attached as <a href="Exhibit 1.6">Exhibit 1.6</a>. "Annual Research Plan" shall mean, for those years occurring after the expiration of the Program Term, a reasonably and consistently detailed statement of the objectives, activities, timetable and budget for the Research Program for such year only.
- 1.7 "Bundled Product" shall have the meaning given in paragraph (b) of the definition of Net Sales.

- 1.8 "Ceased Program" shall mean at least one year has elapsed since Abbott ceased its directed efforts with respect to the applicable Preclinical Program (FTI Program, ED Program or MMPI Program), meaning that Abbott has eliminated the funding for the established research program identified by a core group of researchers dedicated to the applicable Preclinical Program. The continued existence of a researcher separate and apart from such core group shall not affect the determination that a Preclinical Program has ceased.
- 1.9 "Combination Product" shall mean any product containing one or more Program Compounds combined as a single pharmaceutical product with one or more other therapeutically active ingredients.
- 1.10 "Commercially Reasonable Efforts" shall mean efforts which are consistent with those normally used by other pharmaceutical companies with respect to other pharmaceutical compounds or products which are of comparable potential commercial value and market potential at a similar stage of development or product life, taking into account, without limitation, issues of safety and efficacy, compound or product profile, proprietary status, the regulatory environment and the status of the compound or product and other relevant scientific factors.
  - 1.11 "Compound Reports" shall have the meaning given in Section 12.2(i).

CONFIDENTIAL

and the state of the

(

.

, [

- 1.12 "Confidential Information" shall have the meaning given in Section 10.2.
- 1.13 "Delivery System Product" shall have the meaning given in paragraph (d) of the definition of Net Sales.
  - 1.14 "Dollars" or "\$" shall mean United States dollars.
- 1.15 "ED Program" shall mean all of Abbott's discovery efforts to identify compounds (including the identification of pre-clinical and development compounds owned by third parties) which modulate dopamine receptors for the purpose of treating erectile dysfunction.
- 1.16 "Eisai Agreement" shall mean the License Agreement dated June 29, 2000 between Eisai Co., Ltd. and Abbott related to the Program Compound known as ABT-751.
  - 1.17 "Eisai Territory" shall mean the countries listed on Exhibit 1.17 hereto.
- 1.18 "Execution Date" shall mean the date set forth in the introductory paragraph to this Agreement.
  - 1.19 [Intentionally Omitted.]
- 1.20 "FDA" shall mean the U.S. Food and Drug Administration or any successor entity thereto.
- 1.21 "First Commercial Sale" shall mean the first sale of a Product in a given country by Abbott, its Affiliates or Licensees to an unaffiliated third person after Regulatory Approval has been granted in such country.
- 1.22 "FTI Program" shall mean all of Abbott's discovery efforts to identify compounds (including the identification of pre-clinical and development compounds owned by third parties) which act as farnesyl transferase inhibitors for the purpose of treating cancer.
- 1.23 "In-License Agreements" shall mean the Eisai Agreement, the Wakunaga Agreement and the Taisho Agreement.
- 1.24 "International Territory" shall mean all areas of the world outside the U.S. Territory.
- 1.25 "Investigational New Drug Application" shall mean an investigational new drug application filed with the FDA in order to commence human clinical testing of a drug in the United States.

CONFIDENTIAL
JH 008083

all and the State of the State of the White State of the State of the

į

- 1.26 "Licensee" shall mean any party licensed or otherwise authorized in writing by Abbott, its Affiliates or its licensees to market, distribute or sell Products and from whom Abbott receives a royalty or other payment based upon sales of Products by such party, its affiliates or its licensees (it being understood that a party that is a merely a distributor, wholesaler or similar reseller of Products is not a Licensee hereunder). In no case shall Eisai Co., Ltd. or Taisho Pharmaceutical Co., Ltd. be considered Licensees under the terms of the Eisai Agreement or Taisho Co-Development Agreement with respect to the Eisai Territory or Japan, respectively.
- 1.27 "Losses" shall mean any claims, demands, liabilities, costs, damages, judgments, settlements and other reasonable expenses (including attorneys' fees).
  - 1.28 "Milestone Payment" shall have the meaning given in Section 6.3.
- 1.29 "MMPI Program" shall mean all of Abbott's discovery efforts to identify compounds (including the identification of pre-clinical and development compounds owned by third parties) that inhibit matrix metalloproteinase and treat cancer.
- 1.30 "NDA" shall mean a New Drug Application (as defined by the FDA) filed with the FDA for the purpose of obtaining Regulatory Approval of a Product in the U.S. Territory.
  - 1.31 "Net Sales" shall mean:
    - (a) the total gross sales of the Products (or, for purposes of clauses (b) and (c), the Bundled Products and Combination Products), in each case as set forth on the invoices for such sales by Abbott, its Affiliates and Licensees to unaffiliated third parties in any given period, plus, if applicable, the fair market value of all properties and services received in consideration of a sale of the Products (or, for purposes of clauses (b) and (c), the Bundled Products and Combination Products) by Abbott, its Affiliates and Licensees to unaffiliated third parties during such period, less the following deductions directly paid or actually incurred by Abbott, its Affiliates or Licensees during such period with respect to the sale of the Products (or, for purposes of clauses (b) and (c), the Bundled Products and Combination Products) to the extent included in the gross invoiced sales price therefor:
      - (i) discounts, credits, rebates, allowances, adjustments, rejections, recalls and returns;
      - (ii) price reductions or rebates, retroactive or otherwise, imposed by government authorities;
      - (iii) sales, excise, turnover, inventory, value-added and similar taxes assessed on the royalty-bearing sale of Products;

- (iv) transportation, importation, insurance and other handling expenses directly chargeable to the royalty-bearing sale of Products;
- (v) charge backs granted to unaffiliated drug wholesalers; and
- (vi) the portion of management fees paid to unaffiliated group purchasing organizations that relate specifically to the royalty-bearing sale of Products.
- (b) With respect to a Product which is sold together with any other products and/or services in a country at a unit price, whether packaged together or separately (a "Bundled Product"), the Net Sales of such Bundled Product shall first be calculated in accordance with the definition of Net Sales under paragraph (a), and then the Net Sales of such Bundled Product shall be determined on a country-by-country basis as follows:
  - (i) multiply the Net Sales of such Bundled Product in such country by the fraction A/(A+B) where A is the average selling price of such Product in such country when sold separately and B is the total of the average selling prices in such country of each such other product(s) and/or service(s) in such Bundled Product when sold separately; or
  - (ii) if (x) either the average selling price of such Product or the total of the average selling prices of each such other products and/or services in such Bundled Product in such country is not available as of such date or (y) such Product is not sold separately in such country, multiply the Net Sales of such Bundled Product in such country by a percentage determined by the mutual agreement of the Parties which represents the proportionate economic value in such country of such Product relative to the economic value in such country contributed by the other products and/or services in such Bundled Product.
- (c) With respect to a Combination Product, the Net Sales of such Combination Product shall first be calculated in accordance with the definition of Net Sales under paragraph (a), and then the Net Sales of such Combination Product shall be determined on a country-by-country basis as follows:
  - (i) multiply the Net Sales of such Combination Product in such country by the fraction A/(A+B), where A is the total of the average selling prices of the Program Compounds in such



1

Ţ

1

ſ

, *f* 

-6-

Combination Product when sold separately in such country and B is the total of the average selling prices of each other therapeutically active ingredient when sold alone as a pharmaceutical product in such country; or

- (ii) if (x) either the average selling price of all Program Compounds in such Combination Product or the total of the average selling prices of each other therapeutically active ingredient in such Combination Product in such country is not available or (y) such Program Compounds are not sold separately in such country, multiply the Net Sales of such Combination Product by a percentage determined by mutual agreement of the Parties, which represents the proportionate economic value in such country of all Program Compounds in such Combination Product relative to the economic value in such country contributed by all other therapeutically active ingredients in such Combination Product.
- (d) For purposes of this paragraph (d), a "Premium Delivery System" means any delivery system comprising device(s), equipment, instrumentation or other non-ingestible components (but not solely containers or packaging) designed to assist in the administration of a Product, such as the Abbott ADD-Vantage® System. With respect to a Product which is sold together with a Premium Delivery System (a "Delivery System Product") in a country at a unit price, the Net Sales of such Delivery System Product shall first be calculated in accordance with the definition of Net Sales under paragraph (a), and then the Net Sales of such Product shall be determined on a country-by-country basis as follows:
  - (i) if the Product is sold separately without the Premium Delivery System in a country, reduce the Net Sales of such Delivery System Product in such country by the amount that the average selling price of the Delivery System Product in such country exceeds the average selling price of such Product as sold separately in such country; or
  - (ii) if the Product is not sold separately without the Premium Delivery System in such country, reduce Net Sales of such Delivery System Product by an amount, determined by mutual agreement of the Parties, which represents the proportionate economic value in such country added by the Premium Delivery System.
- (e) Net Sales shall not include any sales of Products containing one Program Compound (and no other Program Compound) known as (i) ABT-751 by Eisai Co. Ltd., its affiliates or licensees in the Eisai Territory or (ii) ABT-

1 - . . . .

1 1

773 by Taisho Pharmaceutical Co., Ltd., its affiliates or licensees in Japan. Notwithstanding the foregoing sentence, Net Sales shall include in all instances sales by such parties of such products that are outside such territories, respectively.

- 1.32 "Parties" shall mean Abbott and John Hancock.
- 1.33 "Patents" shall have the meaning set forth in Section 12.2(e).
- 1.34 "Phase I Clinical Trial" shall mean a clinical trial of a Program Compound which utilizes a limited number of human beings preliminarily to address safety and to determine what doses can be safely tolerated.
- 1.35 "Phase II Clinical Trial" shall mean a controlled clinical trial, the primary objective of which is to ascertain additional data regarding the safety and tolerance of one of the Program Compounds and preliminary data regarding such Program Compound's efficacy.
- 1.36 "Phase III Clinical Trial" shall mean one or a series of controlled pivotal studies of a specific Program Compound by administration of such Program Compound to human beings where the principal purpose of such trial is to provide confirmatory safety and efficacy data necessary to support the filing for Regulatory Approval of a Product.
- 1:37 "Preclinical Programs" shall mean the following preclinical and clinical programs with potential backup compounds in accordance with Section 4.3(a): the FTI Program, the ED Program and the MMPI Program.
- 1.38 "Premium Delivery System" shall have the meaning given in paragraph (d) of the definition of Net Sales.
- 1.39 "Product" shall mean any product containing one or more of the Program Compounds as an active ingredient, alone or in combination with other active ingredients (including any Bundled Product and any Combination Product).
- 1.40 "Program Compounds" shall mean (i) the compounds listed on Exhibit 1.40; (ii) the first compound (the selection of which shall be consistent with Abbott using Commercially Reasonable Efforts) from each of the Preclinical Programs to enter Phase I Clinical Trial; (iii) any compounds or products substituted or added by Section 4.3; (iv) all line extensions and formulations of the foregoing; and (v) all analogs, isomers, improvements, derivatives and modifications of the foregoing unless such analog, isomer, improvement, derivative or modification would be considered a new chemical entity and required by the FDA to reenter Phase I Clinical Trial. A compound or product shall be considered a Program Compound regardless of the indication for which it is used.
  - 1.41 "Program Inventions" shall have the meaning given in Section 5.1.

"Program Payments" shall have the meaning given in Section 3.1. 1.42

Document 321-2

- "Program Related Costs" shall mean (i) all direct and indirect costs and expenses that are incurred by Abbott on the Research Program during a given Program Year and allocated in a manner consistent with Abbott's internal, pharmaceutical products division-wide allocation procedures; and (ii) the milestone and license fees paid during a given Program Year or during any extension period of the Program Term by Abbott to (a) Eisai Co. Ltd. (not to exceed Eighteen Million Dollars (\$18,000,000) in the aggregate with respect to the Program Compound known as ABT-751 pursuant to the Eisai Agreement) and (b) Wakunaga Pharmaceutical Co., Ltd. (not to exceed Twenty Seven Million Five Hundred Thousand Dollars (\$27,500,000) in the aggregate with respect to the Program Compound known as ABT-492 pursuant to the Wakunaga Agreement). Any payments made by Abbott to John Hancock pursuant to Sections 6.2 and 6.3(a), (b), (c), (d) and (e) shall constitute Program Related Costs. Any payment made by Abbott to John Hancock pursuant to Section 6.3(f) shall not constitute Program Related Costs. Set forth on Exhibit 1.43 is an example of the calculation of Program Related Costs for a particular Program Compound.
  - "Program Term" shall mean a period of four (4) consecutive Program Years,
- "Program Year" shall mean a period of twelve (12) consecutive calendar months commencing on January 1 of each year, except that the first Program Year shall commence on -the Execution Date and end on December 31, 2001.
  - "Quarterly Reporting Period" shall mean the calendar quarter with respect to the U.S. Territory together with the fiscal quarter ending on the final day of February, May, August and November (as the case may be) with respect to the International Territory. For example, the Quarterly Reporting Period that comprises the second calendar quarter with respect to the U.S. Territory also includes the period from March 1 through May 31 with respect to the International Territory. If Abbott adopts the calendar year as its fiscal year for the International Territory, then the Quarterly Reporting Period for the International Territory shall also be the calendar quarter.
  - 1.47 "Research Program" shall mean all of Abbott's, its Affiliates' and Subcontractors' activities directed towards obtaining Regulatory Approval for the Products, including research, development, safety and efficacy studies, clinical trials, process development, formulation work, regulatory, quality, data collection and analysis and project management.
  - "Regulatory Approval" shall mean: (i) with respect to the U.S. Territory, the receipt of approval from the FDA to market a Product in the U.S. Territory; and (ii) with respect to any country in the International Territory, receipt of the governmental approvals required to market a Product in such country, including any pricing and reimbursement authorization required in such country.

CONFIDENTIAL 380800 HL

(

I

- "Replacement Compound" shall mean a compound (i) made available to Abbott as a result of any transaction involving Abbott or its Affiliates (whether by merger, acquisition or sale of assets or equity, or by license or otherwise), (ii) used for the same class of indications as the Ceased Compound (for example, anti-infectives, cancer, cardiovascular or pain), and (iii) having at least the current and projected potential commercial value to John Hancock as the Ceased Compound.
- "Royalty Term" shall mean, with respect to each Product in each country, a period of ten (10) years from the later of (x) the date of First Commercial Sale of such Product in such country and (y) the two year anniversary of the Execution Date; provided that (i) the obligation to make royalty payments on the Product shall not begin until the two-year anniversary of the Execution Date (and only with respect to Net Sales occurring on or after such date) and (ii) Abbott's obligation to make royalty payments shall cease on December 31, 2015.
  - "Subcontractor" shall have the meaning given in Section 2.4. 1.51
- "Taisho Agreement" shall mean the Co-Development Agreement dated September 30, 1997 between Taisho Pharmaceutical Co., Ltd. and Abbott related to the Program Compound known as ABT-773.
- "Territory" shall mean both the U.S. Territory and the International Territory, excluding the Eisai Territory with respect to the Program Compostad known as ABT-751.
- "U.S. Territory" shall mean the United States of America, excluding Puerto Rico 1.54 and the U.S. Virgin Islands.
- 1.55 "Wakunaga Agreement" shall mean the License Agreement dated December 1, 1999 between Wakunaga Pharmaceutical Co., Ltd. and Abbott related to the Program Compound known as ABT-492.

#### ARTICLE 2 ANNUAL RESEARCH PROGRAM

- Research Program Term. The Research Program shall be conducted by Abbott during the Program Term, and beyond the Program Term until Abbott either abandons development in accordance with the terms hereof or receives Regulatory Approval for each Program Compound, or some combination thereof.
- Research Plan. The Research Program shall be conducted by Abbott in each Program Year in accordance with the Annual Research Plan for such Program Year. The Annual Research Plan will be provided to John Hancock until Abbott either abandons development in accordance with the terms hereof, or receives Regulatory Approval for, each Program Compound in the U.S. Territory, or some combination thereof. The Annual Research Plan shall be prepared

Last printed 3/13/01 1:47 PM

- 2.3 Conduct of Research. Abbott shall use Commercially Reasonable Efforts to conduct the Research Program in good scientific manner and using good laboratory practices, to achieve the objectives of the Research Program efficiently and expeditiously and to comply with all applicable laws and regulations. Notwithstanding anything in this Agreement to the contrary, Abbott does not represent, warrant or guarantee that the Research Program will be successful in whole or in part or result in the registration or commercialization of any pharmaceutical products or that any Products obtaining Regulatory Approval will be a commercial success.
- 2.4 Subcontracting Research. Abbott may subcontract or outsource to Affiliates or third persons (each, a "Subcontractor") any portion of the Annual Research Plan. Consistent with Abbott's past practices, each Subcontractor shall enter into a confidentiality agreement with Abbott and agreements pursuant to which such Subcontractor is required to comply with all applicable laws and regulations, including conducting the Research Program in good scientific manner and using good laboratory practices, with respect to its work on the Research Program. Abbott shall supervise and be responsible under this Agreement for the work of each such Subcontractor on the Research Program and no subcontracting or outsourcing shall relieve Abbott of any of its obligations hereunder.
- Research Reports and Records. Abbott shall, no later than thirty (30) days before the last day of each Program Year, provide John Hancock with a reasonably detailed report setting forth the status of the Research Program and all Program Related Costs expended by Abbott during such Program Year. The Program Related Costs set forth in such report may include good faith estimates with respect to the last three (3) months of the Program Year, provided that the report under this Section 2.5 for the following Program Year contains the actual Program Related Costs for that three (3) month period. Such report shall also contain such other information related thereto as John Hancock may reasonably request from time to time. Abbott shall, and shall cause each Subcontractor to, maintain complete and accurate records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and for purposes of demonstrating compliance with the terms hereof, that fully and properly reflect all work done, results achieved and Program Related Costs expended in performance of the Research Program. The books and records of Abbott and each Subcontractor related to the Research Program, including, without limitation, those related to the expenditure of Program Related Costs, shall be subject to copying, inspection and audit by (and at the expense of) John Hancock at any time and from time to time. Such audit shall occur upon reasonable notice and during normal business hours by an independent auditor selected by John Hancock and reasonably acceptable to Abbott. John Hancock and its independent auditor shall maintain such

Document 321-2

records and information of Abbott in confidence in accordance with Article 10 and shall not use such records or information except to the extent permitted by this Agreement, including any enforcement of the provisions hereof. In the event that such audit reveals any material breach of Abbott's responsibilities hereunder, Abbott shall (i) pay the reasonable fees and expenses charged by such auditor, and (ii) fully and promptly cure such breach.

### ARTICLE 3 RESEARCH FUNDING

John Hancock Program Payments. John Hancock shall make the following installment payments on the applicable payment date (the "Payment Date"), for the applicable Program Year, to Abbott to help support the Research Program (the "Program Payments"):

Payment Date December 1, 2001	<u>Amount</u> \$50,000,000 \$54,000,000	Program Year First Second
December 1, 2002 December 1, 2003 December 1, 2004	\$54,000,000 \$58,000,000 \$52,000,000	Third Fourth

All Program Payments shall be expended by Abbott on Program Related Costs and for no other purpose. If John Hancock has not received at least thirty (30) days prior to the Payment Date both (i) the Annual Research Plan for such year and (ii) the report described in Section 2.5 for the previous Program Year, then John Hancock's obligation to make the Program Payment due on such Payment Date shall be suspended until thirty (30) days have elapsed from the date of John Hancock's receipt of both such Annual Research Plan and report.

- Abbott Funding Obligation. Abbott shall spend on Program Related Costs: (i) during each Program Year, at least the Annual Minimum Spending Target for such Program Year and (ii) at least the Aggregate Spending Target during the Program Term. John Hancock's sole and exclusive remedies for Abbott's failure to fund the Research Program in accordance with this Section 3.2 (but not for any other breach of Abbott's other obligations hereunder) are set forth in Sections 3.3 and 3.4.
- Carryover Provisions. Abbott shall be permitted to change its funding obligations under Section 3.2 only as follows:
  - If in any Program Year Abbott spends on Program Related Costs, the full (a) amount of the Program Payment provided by John Hancock for such Program Year, but does not spend the full amount of the Annual Minimum Spending Target for such Program Year (including any Annual Carryover Amounts from any prior Program Years), Abbott will spend on Program Related Costs the difference between its expenditure on Program Related Costs for such Program Year and the Annual Minimum Spending Target

for such Program Year (the "Annual Carryover Amount") in the subsequent Program Year. John Hancock's obligation to make any Program Payment for such subsequent Program Year, if any, pursuant to Section 3.1, shall be deferred until the time that Abbott has spent and notifies John Hancock that it has spent the Annual Carryover Amount in such subsequent Program Year; and

- (b) If Abbott does not expend on Program Related Costs the full amount of the Aggregate Spending Target during the Program Term, Abbott will expend the difference between its expenditures for Program Related Costs during the Program Term and the Aggregate Spending Target (the "Aggregate Carryover Amount") on Program Related Costs during the subsequent year commencing immediately after the end of the Program Term. If Abbott does not spend the Aggregate Carryover Amount on Program Related Costs during such subsequent year, Abbott will pay to John Hancock one-third of the Aggregate Carryover Amount that remains unspent by Abbott, within thirty (30) days after the end of such subsequent year.
- Termination of John Hancock's Program Payment Obligation. If Abbott: (i) abandons development of all Preclinical Programs and Program Compounds in any Program Year during the Program Term (it being understood that such abandonment need not oecur entirely in one Program Year); (ii) does not expend on Program Related Costs during any Program Year the full amount of the Program Payment made by John Hancock for such Program Year, (iii) does not reasonably demonstrate in its Annual Research Plan, its intent and reasonable expectation to expend on Program Related Costs during the next Program Year an amount in excess of the Program Payment to be provided by John Hancock for such year; or (iv) does not reasonably demonstrate in its Annual Research Plan its intent and reasonable expectation to expend on Program Related Costs during the Program Term an amount in excess of the Aggregate Spending Target, John Hancock's obligation to make any remaining Program Payments for any succeeding Program Years pursuant to Section 3.1 shall terminate. For the avoidance of doubt, the Program Payments for the Program Year in which such event occurs shall still be due and payable, adjusted only as set forth in the next sentence, if applicable. In addition, in the case of either (i) or (ii) above, Abbott shall (not later than the 10th day following such event) pay to John Hancock (x) the amount, if any, by which the Program Payment made by John Hancock for such year (in the case of (i) above meaning the Program Year in which all Preclinical Programs and Program Compounds were finally abandoned), if any, exceeds one-half of the Program Related Costs actually spent by Abbott during that Program Year and (y) such additional amount that, after giving effect to the payments referred to in this sentence, causes the Program Related Costs for all years in the Program Term to date to have been funded one-third (1/3) by John Hancock and two-thirds (2/3) by Abbott.
- 3.5 <u>Hancock Funding Obligation</u>. John Hancock's entire obligation hereunder shall be limited to providing the Program Payments set forth in Section 3.1. Abbott shall be solely

## **Deposition Exhibit 1**

P's Exhibit 32 Part 2 (

Į

responsible for funding all Program Related Costs in excess of the Program Payments from John Hancock.

## ARTICLE 4 PRODUCT RESEARCH AND DEVELOPMENT

- Commercially Reasonable Efforts. Abbott shall be solely responsible for the clinical development, government approval, manufacturing, marketing, sales and distribution of Products. Abbott will use, and will cause each of its Affiliates and Licensees to use, Commercially Reasonable Efforts to pursue the clinical development, government approval, manufacturing, marketing, sales and distribution of Products throughout the Territory. The obligations of Abbott, its Affiliates and Licensees with respect to any Product under this Article 4 are expressly conditioned upon the safety, efficacy and commercial feasibility of each Product, consistent with using Commercially Reasonable Efforts, but no license, assignment or other transfer of rights by Abbott will modify or reduce Abbott's obligations hereunder (except as set forth in Article 14). It is the parties' expectation that under normal circumstances Abbott will file for Regulatory Approval with respect to each Product in Europe within two (2) years from the date of the NDA filing for such Product in the U.S. Territory and in Japan within five (5) years from such NDA filing date; provided, however, that these time frames may be extended or otherwise altered based upon unforeseen circumstances that legitimately impact such regulatory filings in such foreign jurisdictions.
- 4.1, within six (6) months of obtaining Regulatory Approval for a Product in a given country, Abbott, its Affiliates or Licensees shall commence to market and sell such Product in such country. Abbott's obligation to market and sell a Product shall not apply to a Product in any country if Abbott has not commenced or has ceased marketing and selling such Product in such country substantially on account of adverse business or financial conditions caused by the regulatory authorities or other governmental authorities of such country (including not commencing marketing and selling in a country where the regulatory authorities have price or reimbursement approval and the price or reimbursement approval or that proposed by the regulatory authorities or government authorities is unacceptable to Abbott) which causes the marketing and sale of such Product in such country to be contrary to the financial best interests of John Hancock and Abbott; provided, however, that Abbott, its Affiliates or Licensees shall commence or resume marketing and sale of such Product in such country as soon as reasonably practical after such adverse business or financial conditions cease to exist.

4.3 Failure of Program Compound to Progress.

CONFIDENTIAL JH 008093

(a) Preclinical Programs: ED Program, FTI Program and MMPI Program.
With respect to any Program Compound resulting from a Preclinical
Program that Abbott ceases to develop past Phase I Clinical Trial (i.e.,
does not enter a Phase II Clinical Trial) (a "Failed Early Stage Program

Compound"), for which Abbott or its Affiliates has or will have one or more other compounds in such respective Preclinical Program (which includes all in-licensed compounds not yet approved for marketing), the next compound to enter Phase I Clinical Trials from such Preclinical Program shall be considered a Program Compound in all respects hereunder, as of the date of the cessation of such Failed Early Stage Program Compound; provided however, with respect to each Preclinical Program, there shall be no more than three Program Compounds substituted under this Section 4.3(a) (for an aggregate maximum of nine (9) such substitutions for all Preclinical Programs). At the time a Preclinical Program becomes a Ceased Program, Abbott shall have no further obligation to provide a substitute for a Failed Early Stage Program Compound.

- (b) Failure of ABT-492 or ABT-510 to Yield a Compound that Enters a Phase II Clinical Trial. If (i) ABT-492 fails to enter a Phase II Clinical Trial, or (ii) ABT-510 fails to enter a Phase II Clinical Trial, then within six (6) months after the failure of the first such Program Compound to enter a Phase II Clinical Trial, Abbott shall substitute a compound in a Phase II Clinical Trial having a commercial value not less than that currently expected for ABT-492 and ABT-510, respectively (as of the date of execution of this Agreement).
- (c) Cessation as a Result of an Acquired Replacement Compound. If Abbott ceases or substantially ceases developing, marketing or selling any Program Compound (that is in Phase I or beyond) or Product (a "Ceased Compound"), and if such cessation or substantial cessation is a result of Abbott's acquisition of a Replacement Compound, then the Replacement Compound shall be considered a Program Compound and/or Product from the date of such acquisition and the Ceased Compound shall no longer be considered a Program Compound.

In the event that the Replacement Compound has been approved for marketing by the FDA and the Ceased Compound has not been approved for marketing by the FDA as of the date of such acquisition, Section 4.3(d) shall apply and the first paragraph of this Section 4.3(c) shall not apply.

In the event that the Ceased Compound has been approved for marketing by the FDA as of the date of such acquisition, John Hancock shall have the option, in its sole discretion, to have Abbott maximize the commercial value of the Ceased Compound pursuant to Section 4.3(d) instead of having the Ceased Compound be subject to this Section 4.3(c).

CONFIDENTIAL JH 008094 (m.) residenti Shahmilli (

ì

į

1

3 (

- (d) Cessation for Reasons Other than Section 4.3(c). If a Program Compound (that is in Phase I or beyond) or Product becomes a Ceased Compound for any reason not as a result of the acquisition of a Replacement Compound as set forth in Section 4.3(c) above and provided that such Ceased Compound has commercial value, then
  - value, if any, of the Ceased Compound to both parties by outlicensing or divesting such Ceased Compound to a third party; provided, however, if the out-licensing or divestiture of such Ceased Compound requires the approval of Taisho Pharmaceutical Co., Ltd. (in the case of Program Compound ABT-773), Eisai Co., Ltd. (in the case of Program Compound ABT-751) or Wakunaga Pharmaceutical Co., Ltd. (in the case of Program Compound ABT-492), pursuant to the respective In-License Agreement, and such entity does not grant such approval, then Abbott shall within a reasonable period of time but not more than three months substitute a compound (which shall thereupon become a "Program Compound") having at least the current and projected potential commercial value as such Ceased Compound;
  - (ii) John Hancock shall be permitted (but have no obligation) to assist in such out-license and/or divestiture effort; and
  - (iii) Abbott shall remunerate John Hancock based on the sales of such Ceased Compound by the third party that has acquired or licensed the Ceased Compound (the "Acquirer") in a manner most consistent with the allocation that would have applied hereunder had such Ceased Compound not been so out-licensed or divested, i.e., in accordance with the royalties and milestones payable hereunder. The appropriate royalty rate payable to John Hancock shall be determined by adding the Acquirer's Net Sales of the Ceased Compound to the total Net Sales of other Products.
- (e) Divestiture. Notwithstanding anything herein to the contrary, Abbott shall not divest or out-license any Program Compound (which shall mean a sale, license or other transfer by Abbott of the right to develop, market and sell any Product containing such Program Compound either (i) in all of North America or (ii) in the countries of Japan and/or the European Union that have at least two-thirds of the total population of Japan and the European Union), without John Hancock's prior written consent, which consent shall not be unreasonably withheld; provided however, if such Program Compound is being divested as a result of direction from the

١.

ì

i

1 :

Federal Trade Commission to so divest, John Hancock's written consent shall not be required.

- Notice and Information. Abbott shall promptly notify John Hancock upon (f) occurrence of any decision by Abbott to cease or substantially cease developing, marketing or selling any Program Compound or Product. In addition, Abbott shall provide to John Hancock all information reasonably requested by John Hancock related to any Replacement Compound, Program Compound, or Product that is subject to the provisions of this Section 4.3.
- Commercially Reasonable Efforts. Nothing in this Section 4.3 shall lessen (g) any of Abbott's other obligations under this Agreement nor permit Abbott to perform in any manner that is not clearly consistent with using its Commercially Reasonable Efforts hereunder.
- Arm's-Length. Abbott shall not research, develop, manufacture, market, sell, 4.4 distribute, out-license or otherwise treat any Program Compounds or Products differently, as compared to any other Abbott compounds or products, on account of any of John Hancock's rights hereunder. Furthermore, all distribution agreements, licenses, out-licenses and other agreements relating to the research, development, manufacturing, marketing, sale, distribution, licensing, out-licensing or divestiture of and all other transactions involving any Program Compounds or Products to or with any third party (except to Abbott's Affiliates) shall be on arm's-length terms and conditions.
- In-License Agreements. Abbott shall comply in all material respects with the terms and conditions of the In-License Agreements. Abbott shall not amend the In-License Agreements or waive any of its rights thereunder without John Hancock's prior written consent (such consent not to be unreasonably withheld), unless such amendment or waiver does not have and would not have a material adverse effect on John Hancock's interests hereunder. To the extent that Abbott or any of its Affiliates obtains the right to market, distribute or sell Products containing the Program Compound known as ABT-751 in the Eisai Territory, then sales by Abbott, its Affiliates and Licensees of such Products in such territory shall be included in all respects hereunder (including without limitation in Net Sales and the Territory).

### ARTICLE 5 PROGRAM INVENTIONS

CONFIDENTIAL JH 008096

Ownership. As between Abbott and John Hancock, all inventions, innovations, 5.1 ideas, discoveries, technology, know-how, methods, data, applications and products (in each case whether or not patentable) arising from the Research Program or otherwise related to the Program Compounds (collectively, the "Program Inventions") shall be exclusively owned by or assigned to Abbott. Abbott shall not divest, out-license or otherwise transfer any of its right, title

1

i

or interest in or to any Program Inventions which would prevent or impair Abbott's ability to fulfill its obligations to John Hancock under this Agreement.

- Patent Prosecution and Maintenance. To the extent it owns a Program Invention 5.2 or has the contractual right to pursue patent protection for a Program Invention, Abbott will use Commercially Reasonable Efforts to obtain patent protection for the Program Inventions in the Territory. As between Abbott and John Hancock, Abbott shall be responsible for all costs and expenses and control all decisions related to pursuing such patent protection, including the preparation, filing (foreign and/or domestic), prosecution, issuance and maintenance of patent applications or patents covering Program Inventions.
- Enforcement. As between Abbott and John Hancock, Abbott shall have the sole right and authority to enforce the patents or any other rights arising from the Program Inventions 5.3 (including without limitation the Patents) against any infringers. If Abbott initiates any action or lawsuit to enforce such patents or other rights, it shall be solely responsible for the cost and expense thereof. Abbott will promptly notify John Hancock at such time as it becomes aware of any infringement activities and of any such enforcement actions or lawsuit, and Abbott will provide information concerning them as reasonably requested by John Hancock. All moneys recovered upon the final judgment or settlement of any such action or lawsuit, less the out-ofpocket cost and expense thereof, shall be allocated between Abbott and John Hancock proportional to Abbott's lost profits and John Hancock's lost royalties as a result of such infringement. to girther than the second

### ARTICLE 6 MILESTONE PAYMENTS TO JOHN HANCOCK

- 6.1 [Intentionally omitted].
- Management Fee. On December 1, 2002, 2003 and 2004, Abbott shall pay to John Hancock a management fee, each of which shall be in the amount of Two Million Dollars (\$2,000,000).
- Milestone Notification and Payments. Abbott shall promptly notify John 6.3 Hancock of the occurrence any of the following events that give rise to Abbott's obligation to make a payment pursuant to this Section 6.3 (each, a "Milestone Payment"). Except as hereinafter limited, Abbott shall pay the following Milestone Payments to John Hancock in the amounts and at the times set forth below with respect to each Program Compound:
  - One Million Dollars (\$1,000,000) shall be paid within thirty (30) days (a) after the allowance by the FDA of each Investigational New Drug Application for such Program Compound;

(

Į

1

+ I

1

- (b) Two Million Dollars (\$2,000,000) shall be paid within thirty (30) days after the initiation of each Phase I Clinical Trial with such Program Compound;
- (c) Three Million Dollars (\$3,000,000) shall be paid within thirty (30) days after the initiation of each Phase II Clinical Trial with such Program Compound;
- (d) Four Million Dollars (\$4,000,000) shall be paid within thirty (30) days after the initiation of each Phase III Clinical Trial with such Program Compound; and
- (e) Five Million Dollars (\$5,000,000) shall be paid within thirty (30) days after the filing of each NDA with the FDA for such Program Compound.

In addition, except as hereinafter limited, Abbott shall pay the following Milestone Payments to John Hancock in the amounts and at the times set forth below:

- (f) (i) Twenty Million Dollars (\$20,000,000) shall be paid within thirty (30) days after the Regulatory Approval of the first Product in the U.S. Perritory;
  - (ii) Ten Million Dollars (\$10,000,000) shall be paid within thirty (30) days after the Regulatory Approval of the second Product in the U.S. Territory; and
  - (iii) Ten Million Dollars (\$10,000,000) shall be paid within thirty (30) days after the Regulatory Approval of third Product in the U.S. Territory.

The aggregate of Milestone Payments under Section 6.3(a), (b), (c), (d), and (e) for all Program Compounds shall be limited to Eight Million Dollars (\$8,000,000), and once such aggregate limit has been paid, no further payments shall be due and payable under Sections 6.3(a), (b), (c), (d) or (e).

The aggregate of Milestone Payments under Sections 6.3(a), (b), (c), (d) and (e) for all Program Compounds shall be limited to zero dollars (\$0) during the first Program Year, Two Million Dollars (\$2,000,000) during the second Program Year, and Six Million Dollars (\$6,000,000) during the third Program Year, and once such annual limit has been reached for these particular Program Years, no further payments shall be due under Sections 6.3(a), (b), (c), (d) and (e) for the remainder of such Program Year; provided that any amounts that would have been due to John Hancock but for such annual limits shall be paid in subsequent Program Years so long as the Program Compound to which it relates has not been abandoned, divested or out-licensed by Abbott, subject to the Eight Million Dollar (\$8,000,000) limitation set forth above. Subject to

Last printed 3/13/01 1:47 PM

Chillian allah kelilaka

(

1 % 2

the limitations above, the Milestone Payments under Sections 6.3(a), (b), (c), (d) and (e) may be made more than once with respect to each Program Compound.

The aggregate of Milestone Payments under Section 6.3(f) for all Program Compounds shall be limited to Forty Million Dollars (\$40,000,000), and once such aggregate limit has been paid, no further payments shall be due and payable under Section 6.3(f). In addition, Milestone Payments under Section 6.3(f) shall not be paid more than once for any particular Program Compound.

Exhibit 1.40 sets forth the current stage of clinical development for each Program Compound.

#### ARTICLE 7 ROYALTIES

Royalty Rates. Subject to the limitation set forth below, Abbott shall pay to John 7.1 Hancock royalties equal to the following percentages of Net Sales, aggregated on a yearly basis, of all Products in the Territory:

Royalty	percentage

Yearly Net Sales (in millions) of all Products in the Territory

#1. #1 8.5% of those Net Sales and then 4% of those Net Sales and then 1% of those Net Sales and then 0.5% of those Net Sales

up to \$400 in excess of \$400 up to \$1,000 in excess of \$1,000 up to \$2,000 in excess of \$2,000

Net Sales shall be aggregated yearly (i) in the case of the U.S. Territory, on a calendar year basis, together with (ii) in the case of the International Territory, on a December 1 to November 30 basis, in each case consistent with the determination of Quarterly Reporting Periods.

Royalty Term. The duration of the obligation to make royalty payments on each Product shall be determined on a country-by-country basis and shall last for the duration of the Royalty Term in each given country for such Product.

### **ARTICLE 8** ROYALTY REPORTS AND ACCOUNTING

Reports, Exchange Rates. With respect to every Quarterly Reporting Period for 8.1 which Abbott is obligated to pay any royalty hereunder, Abbott shall furnish to John Hancock a single written report for such Quarterly Reporting Period within sixty (60) days after the end of such Quarterly Reporting Period (that is, within sixty (60) days after each March 31, June 30, September 30 and December 31, as the case may be) showing in reasonably specific detail:

- the total gross sales in each country for each Product sold by Abbott, its (a) Affiliates and Licensees in the Territory and the detailed calculation of Net Sales from gross sales in each country for each Product;
- the royalties payable in Dollars, if any, which shall have accrued **(b)** hereunder;
- the dates of the First Commercial Sale of each Product in any country in (c) the Territory during such Quarterly Reporting Period; and
- the exchange rates used in determining the amount of Dollars. (d)

With respect to sales of Products invoiced in Dollars, the gross sales, Net Sales (including all adjustments and deductions permitted to be made hereunder in calculating the same), and royalties payable shall be expressed in Dollars. With respect to sales of Products invoiced in a currency other than Dollars, the gross sales, Net Sales (including all adjustments and deductions permitted to be made hereunder in calculating the same) and royalties payable shall be expressed in their Dollar equivalent, calculated using the Inter Bank rate set forth in the International Report published by International Reports Inc. as Foreign Exchange Rates quoted in New York on the day nearest the last business day of the Quarterly Reporting Period.

#### Audits. 8.2

- Upon the written request of John Hancock and, in the absence of any (a) breach by Abbott hereunder, not more than once in each calendar year, Abbott shall permit John Hancock and an independent certified public accounting firm of nationally recognized standing, selected by John Hancock and reasonably acceptable to Abbott, at John Hancock's expense, to have access during normal business hours to such of the records of Abbott, its Affiliates and Licensees to verify the accuracy of the royalty reports and the amounts and calculation of any payments required hereunder for any year ending not more than five (5) years prior to the date of such request.
- If such accounting firm concludes that additional royalties or other **(b)** payments were owed during such period, Abbott shall have the option to invoke the proceedings of Section 16.7 below or pay the additional royalties or other payments within thirty (30) days after the date John Hancock delivers to Abbott such accounting firm's written report so concluding. The reasonable fees and expenses charged by such accounting firm shall be paid by John Hancock; provided, however, if the audit discloses that the amounts payable by Abbott for any Quarterly Reporting Period are more than one hundred five percent (105%) of the royalties

(

į

, [

**)** [

actually paid for such period, then Abbott shall pay the reasonable fees and expenses charged by such accounting firm.

- Abbott shall cause its Affiliates to, and shall include in each license (c) granted by it relating to a Program Compound or Product a provision requiring the Licensee to, (i) make reports to Abbott, (ii) keep and maintain records of Net Sales made pursuant to such license and (iii) grant access to such records by John Hancock and its accounting firm or other auditor to the same extent required of Abbott under this Agreement.
- All reports and payments not disputed as to correctness by John Hancock (d) within five (5) years after receipt thereof shall thereafter conclusively be deemed correct for all purposes, and Abbott, its Affiliates and Licensees shall be released from any liability or accountability with respect to such reports and payments.
- Confidential Financial Information. John Hancock shall treat all information subject to review under this Article 8, and shall cause its accounting firm to agree to treat all such information, in accordance with the provisions of Article 10.
- 8.4 Accounting Principles. All accounting hereunder, including without limitation all determinations of gross sales, Net Sales (including all adjustments and deductions permitted to be made hereunder in calculating the same), Program Related Costs and all calculations underlying such determinations, shall be made in accordance with generally accepted accounting principles as in effect in the United States, consistently applied.

#### ARTICLE 9 **PAYMENTS**

- Payment Terms. With respect to every Quarterly Reporting Period for which 9.1 Abbott is obligated to pay a royalty hereunder, such royalties shall be due and payable in a single payment within sixty (60) days of the end of such Quarterly Reporting Period (that is, within sixty (60) days of each March 31, June 30, September 30 and December 31, as the case may be). Payment of royalties may be made in advance of such due date.
- Payment Method. All royalties and other payments by Abbott to John Hancock under this Agreement shall be made by bank wire transfer in immediately available funds in accordance with the instructions set forth on Exhibit 9.2 attached hereto or in accordance with such other instructions as John Hancock may give from time to time.
- Late Payments. Each party shall pay interest to the other on the aggregate amount 9.3 of any payments by it that are not paid on or before the date such payments are due under this Agreement, including, without limitation, any disputed payments or payments resulting from any

(.

1 [

) {

audit, at a rate per annum equal to the lesser of (a) the prime rate of interest plus two hundred (200) basis points as reported by Citibank, N.A. in New York, from time to time (with any change in such reported rate being effective immediately for purposes hereof), or (b) the highest rate permitted by applicable law, calculated on the number of days such payments is delinquent until paid in full in cash. All such amounts shall be payable upon demand.

### ARTICLE 10 CONFIDENTIALITY

- 10.1 Nondisclosure Obligations. Except as otherwise provided in this Article 10, during the term of the Agreement and for a period of ten (10) years thereafter, (a) John Hancock shall maintain in confidence in accordance with such procedures as are adopted by John Hancock to protect its own confidential information and shall use only for purposes of this Agreement (including, without limitation, enforcement of the terms hereof), information and data related to the Program Compounds or Products; and (b) John Hancock shall also maintain in confidence in accordance with such policies, and use only for purposes of this Agreement, all information and data supplied by Abbott under this Agreement, which if disclosed in writing is marked "confidential", if disclosed orally is promptly thereafter summarized and confirmed in writing to the other party and marked "confidential", or if disclosed in some other form is marked "confidential."
- described in clause (a) or (b) above shall be referred to as "Confidential Information". John Hancock may disclose Confidential Information as required by applicable law, regulation or judicial process, provided that John Hancock shall, if legally permitted, give Abbott prompt written notice thereof. The obligation not to disclose or use Confidential Information shall not apply to any part of such Confidential Information that (i) is or becomes patented, published or otherwise part of the public domain other than by acts or omissions of John Hancock in contravention of this Agreement; or (ii) is disclosed to John Hancock by a third party, provided such Confidential Information was not obtained on a confidential basis by such third party from Abbott, its Affiliates or Licensees; or (iii) prior to disclosure under the Agreement, was already in the possession of John Hancock, provided such Confidential Information was not obtained directly or indirectly from Abbott, its Affiliates or Licensees under an ongoing obligation of confidentiality; or (iv) is disclosed in a press release agreed to by both parties under Section 10.3 below.
- 10.3 Publicity Review. Without the prior written consent of the other party, neither party shall make any statement to the public regarding the execution and/or any other aspect of the subject matter of this Agreement and John Hancock shall not make any statement to the public regarding any work under the Research Program; provided that, Abbott may make statements to the public regarding work done under the Research Program (without reference to or mention of John Hancock) and the commercialization of any Products resulting therefrom in accordance with its standard business practices. John Hancock and Abbott shall not disclose any

terms or conditions of this Agreement to any third party without the prior consent of the other party, except as set forth above in this Section 10.3 or as required by applicable law, regulation or court order. The parties agree not to issue a press release announcing the execution of this Agreement.

į

) { "

# ARTICLE 11 TERM AND TERMINATION

- 11.1 <u>Expiration</u>. This Agreement shall expire upon satisfaction of Abbott's obligations to pay royalties under Section 7.2 and all other amounts under this Agreement.
- 11.2 <u>Termination: Material Breach</u>. It is the parties' express intent that consideration shall be given to remedying any breach of this Agreement through the payment of monetary damages or such other legal or equitable remedies as shall be appropriate under the circumstances and that there shall only be a limited right to terminate this Agreement under the following circumstances.
  - In the event that the court, in accordance with the procedures set forth in Section 16.2, has issued a ruling that John Hancock has breached its obligation under Section 3.1 of this Agreement (obligation to make payments), and such ruling specified the actions to be taken by John Hancock on account of such breach, and John Hancock has failed to comply with the terms of such ruling within the time period specified therein for compliance and the time for any appeal has expired without the submission of an appeal, then, in addition to all other rights available to Abbott under law and equity, including its right to enforce such ruling in court, Abbott shall have the right to terminate the Agreement as a result of John Hancock's failure to abide by the terms of this Agreement and such ruling.
  - (b) In the event that the court, in accordance with the procedures set forth in Section 16.2, has issued a ruling that Abbott has breached a material obligation under this Agreement, and such ruling specified the actions to be taken by Abbott on account of such breach, and Abbott has failed to comply with the terms of such ruling within the time period specified therein for compliance and the time for any appeal has expired without the submission of an appeal, then, in addition to all other rights available to John Hancock under law and equity, including its right to enforce such ruling in court, John Hancock shall have the right to terminate the Agreement, each as a result of Abbott's failure to abide by the terms of this Agreement and such ruling.

CONFIDENTIAL
JH 008103

(a)

(25) (1) (1) (1) (1) (1) (1) (1)

I

11.3 Effect of Expiration or Termination. Expiration or, if applicable, termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination. The provisions of Articles 8 (Royalty Reports and Accounting), 10 (Confidentiality), 11 (Term and Termination), 12 (Warranties and Indemnification) and 16 (Miscellaneous) shall survive the expiration or termination of this Agreement.

# ARTICLE 12 WARRANTIES AND INDEMNITY

- 12.1 <u>John Hancock Representations and Warranties</u>. John Hancock represents and warrants to Abbott that as of the Execution Date:
  - (a) The execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate John Hancock corporate action. This Agreement constitutes John Hancock's valid and binding legal obligation, enforceable against it in accordance with its terms.
  - (b) The performance by John Hancock of any of the terms and conditions of this Agreement on its part to be performed does not and will not constitute a breach or violation of its organizational documents or any other material agreement or understanding, written or oral, to which it is a party or any law, statute, rule or regulation by which it is bound.
  - (c) No consent, approval, license or authorization of, or designation, declaration or filing with, any court or governmental authority is or will be required on the part of John Hancock in connection with the execution, delivery and performance by John Hancock of this Agreement or any other agreements or instruments executed and delivered by John Hancock in connection herewith or therewith, including, without limitation, any filings pursuant to federal or state securities laws or pursuant to any federal antitrust laws.
  - (d) Neither John Hancock nor any person acting on its behalf (i) has taken or will take any action which would subject this Agreement and the consummation of the transactions contemplated hereby to the registration or qualification requirements of any federal or state securities laws, (ii) has dealt with any broker, finder or other similar person in connection with the transactions contemplated by this Agreement or (iii) is under any obligation to pay any broker's fee, finder's fee or commission in connection with such transactions.
- 12.2 <u>Abbott Representations and Warranties</u>. Abbott represents and warrants to John Hancock that as of the Execution Date:

Last printed 3/13/01 1:47 PM

1\_

į

Į

1 1

- (a) The execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate Abbott corporate action. This Agreement constitutes Abbott's valid and binding legal obligation, enforceable against it in accordance with its terms.
- (b) The performance by Abbott of any of the terms and conditions of this Agreement on its part to be performed does not and will not constitute a breach or violation of its organizational documents or any other agreement or understanding, written or oral, to which it is a party or any law, statute, rule or regulation by which it is bound.
- (c) No consent, approval, license or authorization of, or designation, declaration or filing with, any court or governmental authority is or will be required on the part of Abbott in connection with the execution, delivery and performance by Abbott of this Agreement or any other agreements or instruments executed and delivered by Abbott in connection herewith or therewith, including, without limitation, any filings pursuant to federal or state securities laws or pursuant to any federal anti-trust laws, except those consents, approvals, licenses, authorizations, and other requirements imposed by governmental authorities (both U.S. and foreign) and such declarations and filings with governmental authorities (both U.S. and foreign) required in the normal course of pharmaceutical research, development, marketing and sale.
- (d) Set forth on Exhibit 12.2(d) is the full name, chemical name, detailed description of the stage of development and current status, for each Program Compound. Set forth on Exhibit 1.6 in each Annual Research Plan is a description of projected milestones and dates thereof, projected year of NDA filing, and projected costs to be incurred by Abbott during the Program Term, for each Program Compound. Such projections were prepared in good faith and with due care based on reasonable assumptions, and represent the reasonable estimate of Abbott based on information available as of the date of such projections and as of the date hereof; it being agreed that such projections do not constitute any warranty as to the future performance of the Program Compounds and that actual results may vary from such projections.
- (e) Set forth on Exhibit 12.2(e) is a list and description of all domestic and foreign patents, patent rights, patent applications and all patent applications that are in the process of being prepared that are owned by or registered in the name of Abbott, or of which Abbott is a licensee or in which Abbott has any right, which claim any of the Program Compounds (the "Patents"). Abbott solely owns all of the Patents, except as indicated

į

Į

11

**)** [

on Exhibit 12.2(e). All of the material Patents have been duly filed in or issued by the United States Patent and Trademark Office or the equivalent foreign patent office identified on Exhibit 12.2(e), as the case may be, and have been properly maintained and renewed in accordance with all applicable laws and regulations. With respect to the Patents that it does not own, Abbott has an exclusive and valid license thereunder to develop, make, have made, use, market and sell (with the right to sublicense) the applicable Program Compounds in the entire Territory; provided however, (i) with respect to Italy, Abbott has such rights that are co-exclusive with Eisai Co. Ltd. for the Program Compound known as ABT-751 and (ii) with respect to Japan, Abbott has such rights that are co-exclusive with Taisho Pharmaceutical Co., Ltd. for the Program Compound known as ABT-773. Except with respect to the Preclinical Programs, to Abbott's knowledge, it is not necessary to obtain or license any patents, patent rights, inventions, copyrights, manufacturing processes, formulae, trade secrets, proprietary rights or know-how that it does not currently have in order to (i) develop, make, have made, use, market and sell the Program Compounds or (ii) conduct the Research Program as heretofore conducted and as proposed to be conducted. Except with respect to those Program Compounds that are the subject of In-License Agreements, the Program Compounds are owned exclusively by Abbott, free and clear of any liens or encumbrances of any other person and, to Abbott's knowledge, Abbott does not require the consent of any other person to develop, make, have made, use; market and sell the Program Compounds.

- Except as set forth in Exhibit 12.2(f) (but in any event, as of the Execution (f) Date, such matters are not, and could not reasonably be expected to be material), Abbott has not received any communications alleging that, and no claim is pending or, to the knowledge of Abbott, threatened to the effect that, the operations of Abbott with respect to the Research Program or the Program Compounds infringe upon or conflict with (or will infringe or conflict with) the asserted rights of any other person under any domestic or foreign patent, trademark, service mark, copyright, trade secret, proprietary right or any other intellectual property right, and, except for the Preclinical Programs, there is no material basis known to Abbott for any such claim (whether or not pending or threatened). No claim is pending or, to the knowledge of Abbott, threatened to the effect that any of the Patents are invalid or unenforceable by Abbott, and there is no material basis known to Abbott for any such claim (whether or not pending or threatened). The publication of any material technical information with respect to the Program Compounds developed by and belonging to Abbott is subject to review and approval under Abbott's existing procedures.
- (g) Except for the In-License Agreements and customary employment and consulting agreements with Abbott's employees and consultants, there are

د چ.

(\_

į

ì

Į

no outstanding options, licenses, or agreements of any kind relating to the Patents or any of the Program Compounds or the transactions contemplated by this Agreement, which license the Patents or any technical information developed in the course of the clinical development program to any third party to register, market or sell any of the Program Compounds or Products.

- (h) To the knowledge of Abbott with respect to the Research Program and each of the Program Compounds, Abbott is not now, and in performing its obligations hereunder will not be, in any way making an unlawful or wrongful use of any confidential information, know-how, or trade secrets of any other person.
- (i) Neither this Agreement nor any Exhibit to this Agreement (including the compound reports attached as Exhibit 12.2(i) hereto (the "Compound Reports")) contains any untrue statement of material fact or omits to state any material fact necessary to make the statements contained herein or therein not misleading. There is no fact known to Abbott (other than generally available information concerning the pharmaceutical industry in general) as of the date of this Agreement that has not been disclosed in this Agreement or any Exhibit to this Agreement which has resulted in, or could reasonably be expected to result in, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial) of the Research Program or any of the Program Compounds.
- (j) Neither Abbott nor any person acting on its behalf (i) has taken or will take any action which would subject this Agreement and the consummation of the transactions contemplated hereby to the registration or qualification requirements of any federal or state securities laws, (ii) has dealt with any broker, finder or other similar person in connection with the transactions contemplated by this Agreement or (iii) is under any obligation to pay any broker's fee, finder's fee or commission in connection with such transactions.
- Other than generally publicized actions, proceedings or investigations concerning the pharmaceutical industry in general, there is no action, proceeding or investigation pending or, to the knowledge of Abbott, threatened which (i) questions the validity of this Agreement or any action taken or to be taken by Abbott pursuant thereto or (ii) which has resulted in, or could reasonably be expected to result in, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial) of the Research Program or any of the Program Compounds.

C

Į

- With respect to the Research Program and each of the Program (1) Compounds, Abbott has (and in the future will have) obtained, to the extent permitted by law, from each of its employees, consultants, Affiliates and Subcontractors an agreement that reasonably protects Abbott's interest in the Program Inventions, Program Compounds and Products.
- With respect to each Program Compound, since the date of its respective (m) Compound Report, to the knowledge of Abbott, no condition, circumstance or fact has arisen (other than generally available information concerning the pharmaceutical industry in general) nor has Abbott made any change in the conduct of the Research Program which, individually or in the aggregate, has resulted in, or could reasonably be expect to result in, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial) of such Program Compounds.
- Each In-License Agreement is valid, binding and in full force and effect, (n) and there is no event which has occurred or exists, which constitutes or which, with notice and/or the passage of time, would constitute a material default or breach under any such contract by Abbott or, to Abbott's knowledge, any other party thereto, or would cause the acceleration of any obligation of any party thereto or give rise to any right of termination or cancellation thereof. Abbott has no reason to believe that the parties to each In-License Agreement will not fulfill their obligations thereunder in all material respects or that such parties do not have the right to grant the licenses granted thereunder. Abbott has no reason to believe that it will not fulfill its obligations under the In-License Agreements. Under the Eisai Agreement, neither Abbott nor its Affiliates has the right to market, distribute or sell Products containing the Program Compound known as ABT-751 in the Eisai Territory (with the exception of Italy).
- No Conflict. Abbott and John Hancock represent and warrant that this Agreement does not, and will not, conflict with any other right or obligation provided under any other agreement or obligation that Abbott or John Hancock has with or to any third party.
- Compliance with Law. Each party represents and warrants to the other that it will comply with all applicable laws, regulations and guidelines in connection with its performance of its obligations and rights pursuant to this Agreement, including the regulations of the United States and any other relevant nation concerning any export or other transfer of technology, services or products.
- No Other Warranties. EACH PARTY TO THIS AGREEMENT AGREES THAT, EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS OR

(. !

ì

i

WARRANTIES, AND EACH HEREBY DISCLAIMS ANY OTHER REPRESENTATIONS OR WARRANTIES MADE BY ITSELF OR ANY OF ITS OFFICERS, DIRECTORS, EMPLOYEES, AGENTS, FINANCIAL AND LEGAL ADVISORS OR OTHER REPRESENTATIVES, WITH RESPECT TO THE EXECUTION AND DELIVERY OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, NOTWITHSTANDING THE DELIVERY OR DISCLOSURE TO THE OTHER OR THE OTHER'S REPRESENTATIVES OF ANY DOCUMENTATION OR OTHER INFORMATION WITH RESPECT TO ANY ONE OR MORE OF THE FOREGOING.

- Hancock and its Affiliates, agents, directors and employees harmless, and hereby forever releases and discharges John Hancock and its Affiliates, agents, directors and employees, from and against all Losses related to or arising out of, directly or indirectly, (i) any negligence, recklessness or intentional misconduct of Abbott or its Affiliates, agents, directors, employees, Subcontractors, licensees (including Licensees) or sublicensees in connection with the Research Program, Program Compounds or Products, or (ii) any manufacture, use, storage, distribution or sale of the Program Compounds or Products by anyone, including without limitation all Losses related to any personal injury or death, or (iii) any breach by Abbott of its representations, warranties or obligations hereunder, or (iv) the consummation of the transactions contemplated hereby, except, in each case, to the extent any such Losses are the result of (A) any breach by John Hancock of its representations, warranties or obligations hereunder, or (B) any negligence, recklessness, or intentional misconduct by John Hancock or its Affiliates, agents, directors, employees.
- 12.7 Indemnification Relating to Certain In-Licensed Compounds. Abbott shall indemnify and hold John Hancock and its Affiliates, agents, directors and employees harmless, and hereby forever releases and discharges John Hancock and its Affiliates, agents, directors and employees, from and against all Losses to the extent related to or arising out of, directly or indirectly, the fact that Abbott's rights in the Program Compounds known as ABT-773, ABT-492 and ABT-751 and the Patents and other patent rights, copyrights, trade secret rights and other intellectual property rights related thereto arise from the Taisho Agreement, the Wakunaga Agreement or the Eisai Agreement respectively, rather than being owned by Abbott as with the other Program Compounds. Accordingly, by way of example and without limiting the foregoing, Abbott's indemnification obligation under this Section 12.7 will arise upon (i) any impairment of Abbott's ability to perform its obligations under this Agreement in the entire Territory as a result of Abbott's rights to the Program Compounds known as ABT-773, ABT-442 and ABT-751 arising from the Taisho Agreement, Wakunaga Agreement and the Eisai Agreement, respectively or (ii) a breach by Abbott or any other person of any of the In-License Agreements; except, in each case, to the extent any such Losses are the result of (A) any breach by John Hancock of its representations, warranties or obligations hereunder, or (B) any negligence, recklessness, or intentional misconduct by John Hancock or its Affiliates, agents, directors, employees.
- 12.8 <u>Procedure</u>. If John Hancock or any of its Affiliates, agents, directors or employees (each, an "<u>Indemnitee</u>") intends to claim indemnification under this Article 12, it shall

(

į

ļ

1

į

promptly notify Abbott (the "Indemnitor") of any Loss or action in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have the right to participate in, and, to the extent the Indemnitor so desires, to assume the defense thereof with counsel selected by the Indemnitor; provided, however, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses of such counsel to be paid by the Indemnitor, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceedings. The indemnity obligation in this Article 12 shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld unreasonably or delayed. The failure to deliver notice to the Indemnitor within a reasonable time after the commencement of any such action, if materially prejudicial to its ability to defend such action, shall relieve the Indemnitor of any liability to the Indemnitee under this Article 12 only to the extent arising from the tardiness or absence of such notice, but the omission so to deliver notice to the Indemnitor will not relieve it of any liability that it may have to any Indemnitee otherwise than under this Article 12. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action, claim or liability covered by indemnification under this Article 12, at the expense of the Indemnitor.

- 12.9 Insurance. Abbott shall at its expense maintain, through self-insurance or otherwise, product liability insurance with respect to the development, manufacture, sale and use of Products and Program Compounds in such amounts and on such terms as Abbott customarily maintains with respect to its other similar products. Abbott shall maintain such insurance for so long as it continues to develop, manufacture or sell any Products or Program Compounds, and thereafter for so long as Abbott customarily currently maintains such insurance.
- 12.10 <u>Acknowledgment</u>. Abbott and John Hancock acknowledge that Abbott has not delivered or disclosed the contents of any of the In-License Agreements to John Hancock.

### ARTICLE 13 FORCE MAJEURE

Neither party shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected party including but not limited to fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omission or delays in acting by any governmental authority; provided that such affected party shall provide the other party with prompt notice of the circumstances surrounding such a material failure or delay, after which the parties will amend this Agreement upon terms and conditions that are mutually agreeable to equitably account to the party that does not so fail or delay.

# **Deposition Exhibit 1**

P's Exhibit 32 Part 3

{

l

### ARTICLE 14 ASSIGNMENT

Except as expressly provided hereunder, this Agreement may not be assigned or otherwise transferred, nor may any right or obligations hereunder be assigned or transferred by either party without the consent of the other party; and, in addition, both parties acknowledge and agree that the obligations of Abbott hereunder are personal to Abbott and that Abbott is uniquely qualified to perform them; provided, however, that either party shall be obligated to assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger or consolidation or change in control or similar transaction and in such event such party shall cause its successor or transferee in such transaction to assume all of the obligations of such party. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Notwithstanding the foregoing, John Hancock shall have the right to assign its rights (but not its obligation to make payments under Section 3.1) in whole or in part (provided that, any assignment in part shall mean an assignment of a pro rata share of the entirety of John Hancock's rights hereunder) without Abbott's consent (and following any such assignment all references to John Hancock herein shall include any such assignee), provided that: (i) each assignee of such rights must be a bank, insurance company or other institutional investor; (ii) there shall be no greater than five (5) assignees, (iii) if any such assignee is located outside the United States John Hancock shall notify Abbott at least sixty (60) days in advance, (iv) if any claim arises with respect to Abbott's failure to make payments, then during the term of the Research Program (but in any event not longer than four years from the date hereof), any such claim must be brought by John Hancock, and not an assignee. In soliciting potential assignees for such right to payments, John Hancock shall not disclose any Confidential Information hereunder to more than ten (10) potential assignees. Any potential assignee to whom John Hancock discloses Confidential Information must have executed a confidentiality agreement no less stringent than Article 10 hereof. Furthermore, if John Hancock plans to exercise its right of assignment hereunder, John Hancock shall first notify Abbott of such plans in writing. Abbott shall have the first right to negotiate the purchase of any such assignment rights. If within fifteen (15) days after receipt of such notice the parties have not agreed upon the principal terms of such arrangement or if within forty-five (45) days after receipt of such notice the parties have not executed a final written agreement reflecting such arrangement, then John Hancock shall have no further obligations to Abbott with respect to such first right of negotiation.

### ARTICLE 15 SEVERABILITY

CONFIDENTIAL JH 008111

Each party hereby agrees that it does not intend its execution and delivery hereof or its performance hereunder to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. If and to the extent any term or provision of this Agreement is held to be invalid, illegal or unenforceable by a court or other governmental

į

夏野王、北西、南

ordin militaria.

影 流 人

authority of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement, which shall remain in full force and effect. The holding of a term or provision to be invalid, illegal or unenforceable in a jurisdiction shall not have any effect on the application of the term or provision in any other jurisdiction.

### ARTICLE 16 MISCELLANEOUS

16.1 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the parties hereto to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery, U.S. first class mail or courier), U.S. first class mail or courier, postage prepared (where applicable), addressed to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to John Hancock: John Hancock Life Insurance Company

200 Clarendon Street, T-57

Boston, MA 02117

Attention: Bond & Corporate Finance Group

Telephone: 617-572-9624

Fax: 617-572-1628

copy to: John Hancock Life Insurance Company

200 Clarendon Street, T-50

Boston, MA 02117

Attention: Investment Law Division

Telephone: 617-572-9205

Fax: 617-572-9268

and, if it relates to making or not making a royalty payment or Milestone Payment hereunder,

copy to: John Hancock Life Insurance Company

200 Clarendon Street Boston, MA 02117

Attention: Manager, Investment Accounting Division, B-3

Fax: 617-572-0628

CONFIDENTIAL JH 008112

ing the state of t

If to Abbott:

į

į

1

) £

Abbott Laboratories Dept. 309, Bldg. AP30 200 Abbott Park Road

Abbott Park, IL 60064-3537

Attention: President, Pharmaceutical Products Division

Telephone: Fax:

847-938-6863 847-938-5383

copy to:

General Counsel Abbott Laboratories Dept. 364, Bldg. AP6D 100 Abbott Park Road Abbott Park, IL 60064-6020 847-937-8905 Telephone:

Fax:

847-938-6277 .

- Applicable Law. The Agreement shall be governed by and construed in accordance with the internal laws of the State of Illinois. With respect to any action hereunder, Abbott, to the extent that it may lawfully do so, hereby consents to service of process, and to be sued, in the Commonwealth of Massachusetts and consents to the exclusive jurisdiction of the courts of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts, as well as to the jurisdiction of all courts to which an appeal may be taken from such courts, for the purpose of any suit, action or other proceeding arising out of any of its obligations hereunder or thereunder or with respect to the transactions contemplated hereby or thereby, and expressly waives any and all objections it may have as to venue in any such courts. Abbott further agrees that a summons and complaint commencing an action or proceeding in any of such courts shall be properly served and shall confer personal jurisdiction if served personally or by certified mail to it at its address for notices as provided in this Agreement or as otherwise provided under the laws of the Commonwealth of Massachusetts. THE PARTIES EACH IRREVOCABLY WAIVE ALL RIGHT TO A TRIAL BY JURY IN ANY SUIT, ACTION OR OTHER PROCEEDING INSTITUTED BY OR AGAINST IT IN RESPECT OF ITS OBLIGATIONS HEREUNDER OR THEREUNDER OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.
- 16.3 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with respect to the subject matter hereof heretofore made are expressly merged in and made a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both parties hereto.
- Headings. The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several CONFIDENTIAL Articles and Sections hereof.

JH 008113

C

1

) I

- 16.5 <u>Independent Contractors</u>. It is expressly agreed that John Hancock and Abbott shall be independent contractors and that the relationship between the two parties shall not constitute a partnership, joint venture or agency. Neither John Hancock nor Abbott shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other party to do so.
- 16.6 Performance By Affiliates, Licensees and Subcontractors. The parties recognize that Abbott may carry out certain obligations under this Agreement through performance by its Affiliates, Licensees and Subcontractors (but in no event shall that relieve Abbott of any of its obligations hereunder). Abbott guarantees that the activities of its Affiliates, Licensees and Subcontractors under this Agreement shall comply with this Agreement.
- 16.7 <u>Dispute Resolution</u>. The parties shall attempt to amicably resolve disputes arising between them regarding the validity, construction, enforceability or performance of the terms of this Agreement, and any differences or disputes in the interpretation of the rights, obligations, liabilities and/or remedies hereunder, which have been identified in a written notice from one party to the other, by good faith settlement discussions between the President of Abbott's Pharmaceutical Products Division and a Managing Director of John Hancock or his designee. The parties agree that, prior to filing any lawsuit regarding any dispute that arises in connection with this Agreement (with the exception of any action demanding a preliminary injunction), such representatives shall meet and attempt to amicably resolve such dispute within thirty (30) days after the receipt of such written notice.
- 16.8 Waiver. The waiver by either party hereto of any right hereunder or the failure to perform or of a breach by the other party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other party whether of a similar nature or otherwise.
- 16.9 <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[the remainder of this page is intentionally blank]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

JOHN HANCOCK LIFE INSURANCE COMPANY

ABBOTT LABORATORIES

į

Name: Stephen J. Blewitt

Title: Managing Director

Date: March 13, 2001

Name: Jeffrey M. Leiden, Ph.D., M.D. Title: Executive Vice President, Pharmaceuticals

and Chief Scientific Officer

Date: March 13, 2001

JOHN HANCOCK VARIABLE LIFE INSURANCE COMPANY

Name: Stephen J. Blewitt

Title: Authorized Signatory

Date: March 13, 2001

INVESTORS PARTNER LIFE INSURANCE COMPANY

Name: Stephen J. Blewitt

Title: Authorized Signatory

Date: March 13, 2001

-36-

#### EXHIBIT 1.6

### FIRST ANNUAL RESEARCH PLAN

CONFIDENTIAL JH 008116

. [

Ketolide Oral & IV (ABT-773) Annual Development Plan Exhibit 1.6

) į

**)** [

Therapeutic Area	Anlibacterial					-	
Indications	Adult Tablet:	Community-acc	quired respirator	y infections.	.V.: Step-down	therapy in community-	Adult Tablet: Community-acquired respiratory infections. 1.V.: Step-down therapy in community-acquired hospitalized pneumonia.
Description	- ABT-773 is a Product will II ABT-773 will waintains clack Cover key G - Tablet dosing - Tablet: 6 da - incidence of - COGS targe	be potent ketolid be available as l'address the m an's claim of "S let staint strail let session strail ys for ABECB. Gi side effects (\$2,500/kg at is	- ABT-773 is a potent ketolide with strong activity against most macrolide resistant strair - Product will be available as tablet and IV formulation.  - ABT-773 will address the major unmet medican needs of increasing resistance to curre-Maintains clairs claim of "Spans the spectrum" (G+, G-, atypicals).  - Cover key G+ resistant strains (S. preumonia, S. pyogenes).  - Tablet dosing is 150mg QD or 150mg BID dosing based on severity of Indications.  - Tablet: 5 days for ABECB, pharynglits, 10 days for AMS and CAP.  - Incidence of Gt side effects equal to clari (assuming comparable drug levels to tablet).  - COGS target \$2,500/kg at launch for tablet.	livity against in mulation. ical needs of li num" (G+, G-, it., S. progent foshing based to days for AMS is suming comp	iost macrolide racestrates atypicals). ss). nn severity of Inc. and CAP. sarable drug lev	esistant strains; while riance to current empiric dications.	<ul> <li>ABT-773 is a potent ketolide with strong activity against most macrolide resistant strains; while maintaining the broad spectrum coverage of darithromycin.</li> <li>Product will be available as tablet and IV formulation.</li> <li>ABT-773 will address the major unmet medical needs of increasing resistance to current empiric agents, particularly S. pneumonia.</li> <li>Maintains clarf sclain of "Spans the spectrum" (G+, G-, atypicals).</li> <li>Tablet dosting is 150mg QD or 150mg BID dosting based on severity of indications.</li> <li>Tablet dosting is 150mg QD or 150mg BID dosting based on severity of indications.</li> <li>Tablet E days for ABECB, pharynglits, 10 days for AMS and CAP.</li> <li>Incidence of Gt side effects equal to clarf (assuming comparable drug levels to tablet).</li> <li>COGS target \$2,500/kg at launch for tablet.</li> </ul>
Current	Milestone	Tablet Date	IV Date				Sponding \$\$
Time Line	Phase I Phase Ilb	101997 301999	102001 N/A			5 ;	Project-to-Date-Spending (thru '00)
	Phase III	402000	402001			*,	2004 Current Projection (Plan) 81.5
	Launch	102004	202004			-⊋*.	
						.,	* See page 2 for detail.
Projected Spending	2000	2001	2002	2003	2004	2005 Total	Te
by Year	74.1	91,5	69.0	45.0	32.0	22.0 333.6	
C							
ONFIDENTIAL JH 008117							

) [ .

		2001 P	lan Develc	2001 Plan Development Cost Summary	ummary			
Program Status	1999	2000			2003			
	Q1 Q2	01 02 03 04	ē	02 03 04 01 02 0	Q1   Q2   Q3   Q4   Q1   Q2   Q3   Q4	3 04 01 02 03 04	<u></u>	
Phase IIb (Tablet) Phase III (Tablet)			SHEWARDS OF	ACCHERACE SECTION CONTINUES		<del>(</del>		
				Table! NDA Filing	)A Filho	) Tablel Launch		
				1				
Major Development Activities and Cost	2515		Total	Enrolled			2000 AGU	2001 Pian
Clinical Program			Patients	9/29/00	Start	End	Cost	Cost
Phase IIB	Phase IIB Studies (3 Indications)	ons)	006	863	Sep-99	Jun-00	\$5,017	<b>\$</b>
E esend	Phase III (4 Indications)	<b>,</b>	5.440	0	Nov-00	May-02	\$10,885	\$41,051
Japan Studie	rdies		TBD	0	Oct-00	Dec-01	\$1,723	\$4,000
Pediatric	Pediatric PK/PD / Taste Testing Studies	ling Studies	24	. 42	Mar-00	Sep-00	\$575	\$0
External S	External Special Population Studies	Studies	36	117	Mar-00 ·	Mar-01	\$1,686	\$63
Internal Bi	Internal Bio Studies (Phase I Center)	(Center)	250	162	Jan-01	Dec-01	\$2,524	\$2,150
Microbiology	ogy Grants	•	Ϋ́Z	N/A	Jan-01	Dec-01	\$2,000	\$2,000
Venture	ure Management						\$5,436	\$6,863
Enrol	European Venture Research	sarch					\$1,133	\$1,474
Data	Dala Management/Stalistics	istics		•			\$3.519 \$34.498	\$5,037 \$62,638
Chemistry, Manufacturing, and Controls (CMC)	trois (CMC)							
							2000 AGU	. 2001 Plan
Formulation & Analytical							\$6,676	\$5,594
Bulk Drug / Process							\$24,529	\$16,432 \$22,026
Origina Safety Support	Oncolna Onio Safety support Inclinding	afety event b	ncluding.				2000 AGU	2001 Plan
	Long Term	Long Term Toxicity Studies	88				\$3,374 \$3,374	\$1,749 \$1,749
							2000 AGU	2001 Plan
Other Support Costs	Discovery				ć		\$2,886	52,418
	Regulatory Ans Medical Affairs	y Analis / Rese Hairs		Kegulatory Analis / Kesearch CA / Investigational Drug CA Medical Affairs	§		\$679	\$887
	Uner Total Pro	1					574.100	\$91.500
	total Program	gram					THE PARTY OF THE P	

Ċ.

**)** (

Endothelin (ABT,4627) Annual Development Plan Exhibit 1,6

Therapoulic Area	Oncology							
Indications	- Hormone Re - Potential for	<ul> <li>Hormone Refractory Prostate Cencer</li> <li>Potential for use in early Prostate Cancer and other cancer types</li> </ul>	Cancer state Cancer and	fother cancer	lypes	`		
Description	- ABT-627 is Abbott's - ABT-627 is seeking - ABT-627 will probal - Well tolerated as ci - Oral administration - No major drug inter - Demonstrated cost	- ABT-627 is Abbout's leading endothelin antagonist receptor - ABT-627 is seeking an Indication for the treatment of horma - ABT-627 will probably be used with current therapies - Well folerated as chronic therapy - Oral administration - No major drug interactions with drugs commonly used in el-	endothelin anta; ation for the trea ed with current ti repy tith drugs comm ness at filing	yonist receptor timent of hormi herapies only used in el	one refractory (	n antagonist receptor te treatment of hormone refractory prostate cancer irrent therapies commonly used in elderly population or hormonal therapy ling	herapy	
- Transit	Milestone Phase I	Date 201996 401997				,	AH F	Spending Project-to-Date-Spending (thru '00) 127.6
Time Line	Phase III NDA FIIIng Launch	402000 202004 402004					``	2001 Current Projection (Plan)
·								* See page 2 for detail.
Projected Spending	2002	2001	2002	2003	2004	2005	Total	
by Year PC*	PC. 13.0 PE' NA FE' NA	38.0 8.0 5.0	40.0 6.0 3.0	33.0 5.0 0.0	20.0 0.0 0.0	0.0	154.0 17.0 8.0	
C	End of Ph	End of Phase II meeting with FDA cancer indications ongoing. 2001	ilh FDA just cor g. 2001 range t	npleted. Budg	iet impact still i ling on outcom	iust completed. Budgel impact still in process plus discussion of other range \$35-40 depending on outcome of discussion.	discussion of	other

(

2 1998 1999 1999 1999 1999 1999 1999 199	0000	20	2001	2002	2003	2004	
01   02   03   04   01   02   03	0007						
	01 00 10	01 0	02 03 04	5	04 01 02 03	Q4 Q1 Q2 Q3 Q4	
		× × × ×	٠ ١			+	
Phase III	<u> </u>					NDA	 Launch
or Development Activities and Costs			-			2000 ACII	2001 Plan
	Total	Enrollment				00W 0007	
nical Program	wi	as of 8/31/00		Start	End Dec 2000	Cost	<u> </u>
European Prostate Cancer Study	204	285	- ر	Oct-1997	Jun 2001		: :
Open Extension of 500 & 594 Studies	300	199	<b>-</b>	Jun-1998	1007-unf	ŧ	•
Refractory Malignancies	30	34	-	Jul-1999	10.2001	\$250	167.918
Phase III Pivotal Studies	2,000	>		1007		\$7.5	\$18
Other Studies / EVR						56,447	196,361
Venture Management		•					\$518
Clinical Pharmacology Support (Drug Interaction Studies) Data Management/Statistics		· -	÷			\$2,156 \$2,261	\$2,691 \$26,382
(C) (C) signature of the signature of th						2000 AGU	2001 Plan
iciliistry, ivasituracturing, and controls (cirve)		•	-			\$1,159	57,147
Formulation & Analytical Bulk Drug / Process						5350	\$1,400 \$8,547
						2000 AGU	2001 Plan
rug Safety Support Ongoing Drug Safety support including clinical program support	port	- 4	· .·			\$661	\$2,060
4						2000 AGU	2001 Plan
ther Support Costs		t v	,			\$186	\$129
Discovery			ا ا			\$134	\$207
Medical Affairs		•				\$170	\$215
						27.03	2460
						213,000	238.000
Total Program TOTAL TOTA							

CCM (ABT-594) Annual Development Plan Exhibit 1.6

) [

Therapeutic Area	Neuroscience					4				
Indications	ABT-594 primary target indication is the treatment of neuropathic pain (NP).	ry target indicat	on is the treatm	ent of neuropa	hic pain (NP).					
Description	- ABT-594 is a non-opioid, non-NSAID analgasic that is a poient and selective neuronal nicotinic receptor modulator.  - ABT-594 is effective in nociceptive pain and neuropathic pain.  - ABT-594 is expected to have a better side effect profile than opioids, no tolerance, no abuse, and no DEA scheduling.  - Pre clinical data show ABT-594 to be 30 to 100 times more potent and equally efficacious to morphine in treating mode models of pain.  - ABT-594 has a unique mechanism of action which may enable use in combination with other analgasics as well as more slow onset of action (approx. 1.5 - 3 hours) at tow doses tested may suggest limited utility in acute pain types.  - Favorable safety profile.  - Oral formulation, BID dosing.	-ABT-594 is a non-opioid, non-NSAID analgesic that is a poient and selective neuronal nicotinic receptor modul -ABT-594 is effective in nociceptive pain and neuropathic painABT-594 is expected to have a better side effect profile than opioids, no tolerance, no abuse, and no DEA sch - Pre clinical data show ABT-594 to be 30 to 100 times more potent and equally efficacious to morphine in treati models of pain ABT-594 has a unique mechanism of action which may enable use in combination with other analgesics as we - Slow onset of action (approx. 1.5 - 3 hours) at low doses tested may suggest limited utility in acute pain types Chal formulation, BID dosing.	NSAID enelges pilve pain and r a better side elf 94 to be 30 to 11 anism of action v 1.5 - 3 hours) a	ic that is a pole teuropathic pal ect profile than 30 times more which may ena it fow doses tea	inl and selective.  n. opioids, no toke potent and eque bie use in comb	a neuronal nicoli rrance, no abusi illy efficacious to ination with othe st fimiled utility is	inic receptor i e, and no DE. o morphine in rr enalgesics n ecule pain I	- ABT-594 is a non-opioid, non-NSAID analgesic that is a potent and selective neuronal nicotinic receptor modulator.  - ABT-594 is effective in nociceptive pain and neuropathic pain.  - ABT-594 is expected to have a better side effect profile than opioids, no tolerance, no abuse, and no DEA scheduling.  - Pre clinical data show ABT-594 to be 30 to 100 times more potent and equally efficacious to morphine in treating moderate to severe pain in several well characterized animals.  - ABT-594 has a unique mechanism of action which may enable use in combination with other analgesics as well as monotherapy.  - Slow onset of action (approx. 1.5 - 3 hours) at low doses tested may suggest fimiled utility in acute pain types.  - Favorable safety profile.  - Oral formulation, BID dosing.	i well characlerized at	imai
Current Time Line	Milestones IND Filing Phase I Phase II Phase III NDA Filing Launch	Date 401998 301997 301998 402001 302003 302004	COL	Luck	7000	The state of the s		Spending Project-to-Date-Spending (thru '00) 2001 Current Projection (Plan) ' See page 2 for detail.	97.3 35.0°	
Projected Spending by Year	14.4	35.0	<b>2002</b> 45.0	32.0	<b>2004</b> 15.0	<b>2005</b> 12.0	<u> </u>			
CONFIDENTIAL JH 008121										

ABT-594 '. 2001 Plan Development Gost Summary

(

1 **[** 

		2001 Plan	2001 Plan Development Cost Summary	Jost Sum	กากรว				
Program Status	1997	61 8661	1999	2000	2001	2002		L	_
	0102 03 04 01 0	04	02 03 04 01 02	02 03 04	01 02 03	02 03 04 01 02 03 04		01  02 03 04 01 02  03   04	
t esche								4	
		THE PART AND THE PART OF THE P	1000円を2000円の				]	Launch	
II DONII I		Control and the latter of the latter			NAME OF TAXABLE PARTY.	· · · · · · · · · · · · · · · · · · ·	范 第一次 20		
l'nase III		-			-	1,011 75-1 1-01	<b>*</b>		
							NDA filing	lling	
Maior Development Activities and Costs	osiso			٠,					
		Total	Enrolled	٠.			2000 AGU	2001 Plan	
Clinical Program		Patients	8/30/00	, e. C.	Slart	End	Cost	Cost	
			1		90	00	000	5	
Phase IIb Neuropathic Pain	athic Pain	320	22	7	Apr-00	00-AUN	000,04		
Phase I Studies		281	< Z	_	Feb-01	Sep-02	2	57,175	
Phase IIb Ostenarthritis	thritis	575	٧X		Jun-03	Nov-01	20	\$5,261	
Phase III Studies	•	3,400	VΝ		Oct-01	Muy-04	20	\$6,370	
	1,4,000,000,000						54.493	\$5,137	
	Venture Management	Than I Contac Studies	5	٠			22.10	\$5,042	
Cluncal t	Cidical Finalisacology Support (Finase 1 Center Steeles)	liese i Celliei Staare	?				8	\$103	
module A val	EVA Support						\$646	\$2.197	
Chia Ma	an lagenticino oranio inco						\$8,349	\$26,241	
Chemistry, Manufacturing, and Controls (CMC)	trols (CMC)								
Packaging of	Packaging of Phase IIb clinical supplies and Phase III formulation development and pre-scale un	es and Phase III					2000 AGU	2001 Plan	
-Commonta	Thermoleting & Ameliainal	•					\$1,624	.\$3,268	
60 W. C	Pully Dair / Process						\$359	\$950	
Cliffer							\$785	\$1.209	
							\$2,768	\$5,427	
Drug Cafaty Support	Ossaina Date Safely support including:	upport including:					2000 AGU	2001 Plan	
	Toxicity, carcinogenicity, Clinical Program Support	Toxicity, carcinogenicity, and animal pharmacology studies Clinical Program Support	harmacology stud	So			22,417	21.402	
							2000 AGU	2001 Plan	
Other Support Costs	Discovery			Ť			\$50	\$154	
Come adding and	Medical Affaire						\$95	\$152	
٠	Remistory Affair	Repulatory A ffairs / Research OA / Investigational Date OA	netinational Date	Ý.			\$155	\$1,147	
C	Other	ý					\$552	2482	
Ö				,			981.713	\$35,005	
JH	Total Program						NAME OF		
FIDENTIAL 1 008122									
	•								

Quinolone (ABT-492) Annual Development Plan Exhibit 1.6

Indications - Com - AB and and - Com Description - Prof	nmunity acou	shead enemiratory	nosocomial pr	eumonia, comp	Icated and ur	complicated				
		Tional desiries	Colonian mission				I urinary tract a	<ul> <li>Community acquired respiratory, nosocomial pneumonia, complicated and uncomplicated unhary tract and skin/soft lissue infections.</li> </ul>		
- Tar - CO	3T-492 is a p d quinolone of mmercial obj silminary in-v oduct will be a oduct will be a rgeting 5-7 d rgeting 5-7 d	<ul> <li>ABT-492 is a poient broad-spectrum quinolone with activity against Gran and quinolone resistant stellas of S. poteumo.</li> <li>Commercial objective is "Trovan-like" activity with "Levaquin-like" safety.</li> <li>Commercial objective is "Trovan-like" activity with "Levaquin-like" safety.</li> <li>Prefiliminary in-vitro safety assays suggest good safety profile.</li> <li>Prefiliminary in-vitro safety assays suggest good safety profile.</li> <li>Product will be available in tablet and injectable formulations.</li> <li>Targeting QD dosing for both formulations (not confirmed).</li> <li>Targeting 5-7 day dosing for most indications (not confirmed).</li> <li>COGS at \$1,500-3,200/kg at launch pending chemistry optimization.</li> </ul>	of Statements.  In-like" activity v ys suggest goor et and injectabl  munalions (no ost indications (	unolone with activity as teumo.  activity with "Levaquin-ili activity with "Levaquin-ili iest good safety profile. Injectable formulations. Injectable formulations. In for confirmed).  calions (not confirmed).  calions (not confirmed).	painst Gram+, ke" safety tation.	Gram-, and	alypical palho	<ul> <li>ABT-492 is a potent broad-spectrum quinolone with activity against Gram+, Gram-, and atyptical pathogens, including most penicitin, macroline, and quinolone resistant strains of S, protum.</li> <li>Commercial objective is "Trovan-lite" activity with "Levaquin-lite" safety.</li> <li>Preliminary in-vitro safety assays suggest good safety profile.</li> <li>Product will be available in tablet and injectable formulations.</li> <li>Targeting QD dosing for both formulations (not confirmed).</li> <li>Targeting 5-7 day dosing for most indications (not confirmed).</li> <li>Targeting 5-7 day dosing at launch pending chemistry optimization.</li> </ul>		
	Milestone	Date						Spending	\$3	
Time Line Phase I		4Q2000 3Q2001						Project-to-Date-Spending (thru '00)	11.3	
Phase II		302002								
. NDA FIII	NDA Filing Leunch	402004						2001 Current Projection (Plan)	25.0*	
		··						See page 2 for detail.		
								-		
Projected Spending	2002	2002	2002	2003	2004	2005	· Iotal			
by Year	8.9	25.0	75.0	100.0	52.0	11.0	269.8			

€.

) [

Quinolone (ABT-492)

Program Status 2000   2000   01   02   03   04   01   03   03   03   04   04   05   05   05   05   05   05	2 2	2001 Plan Development Cost Summary  001	ummary 2004 3 Q4 Q1 Q2 Q3 Q4	2005   Q4   Q1   Q2   Q3   Q4	3104	
Phase II Phase III Phase III					<b>k</b>	
	I			NDA	Launch	
Major Development Activities and Costs	1-1-L	7 - 3 - 3 - 3			1104 0000	1000
Clinical Program	i otal Patients	Enrolled 8/31/2000	Start	End	Zoou AGU Cost	2001 Plan Cost
Phase 1						
Single Rising Dose / Food Effects in	is in Healthy Volunteers 116	0	Nov-00	Jan-01	\$500	\$170
Multiple Rising Dose in Healthy Volunteers	Volunteers 60	0	Nov-00	Apr-01	\$500	\$300
External PK Studies	A/N	0	Apr-01	Sep-01	0\$	\$800
Microbiology Studies	N/A	N/A	Jan-01	Dec-01	\$0	\$713
Phase IIA - AECB	250	0	Aug-01	Apr-02	20	\$2,083
Phase IIB - CAP	250	0	Nov-01	Jul-02	80	\$833
Venture Managemen					\$201	\$1,320
European Venture Research	e Research	•			\$28	\$58
Phase I Center		-			\$70	\$130
Data Management/Statistics	nVStatistics	-			\$53	\$489
					\$1.352	\$6.996
Chemistry, Manufacturing, and Controls (CMC)						
					2000 AGU	2001 Plan
Bulk Drug / Process		·			\$598	\$7,872
		•			\$593 \$1.191	\$961 \$8.833
Drug Safety Support Ongoing D	Ongoing Drug Safety support including:	i.			2000 AGU	2001 Plan
Toxicity	city Studies	عی د ۱	-		\$1,941	\$2,331 \$2,331
Other Support Costs Dieg	Discovery				2000 AGU	2001 Plan
	Reg. / Res. Quality Assurance / Investigational Drug QA	igational Drug QA			\$110	\$534
ı	lical Affairs ar				<b>0</b>	\$35 547
ON	Milestone Payments (initiation of Phase IIA)	se IIA)			200	\$3,000
FIC					\$2,316	\$5.84U
ŒI	Total Program	•	1		\$6,890	\$25,000
NTI 124		,				
AL						

TSP (ABT-510) Annual Development Plan Exhibit,1.6

: 1

) E

Therapeutic Area	Oncology									
Indications	Solid tumors a	Solid tumors such as lung, breast, overy, bladder and pancreas.	ast, ovary, blac	ider and pancer	as.					
Description	- Thrombospondin peptide - Novel anti-englogenesis ( - Parenteral dosing - ABT-510 is seeking an in - Mechanism may prevent supplying blood vessels	- Thrombospondin peptide - Novel anti-anglogenesis agent - Parenteral dosing - ABT-510 is seeking an indication for the treatment of solid fumors - Mechanism may prevent the growth of tumors and prevent the spresuppying blood vessels	nt stlon for the tre growth of tumc	siment of solid	lumors the spread of 1	metastases by	preventing or	<ul> <li>Thrombospondin peptide</li> <li>Novel antil-anglogenests agent</li> <li>Parenteral dosing</li> <li>ABT-510 is seeking an indication for the treatment of solid tumors</li> <li>Mechanism may prevent the growth of tumors and prevent the spread of metastases by preventing or inhibiting the growth of nutrient supplying blood vessels</li> </ul>		
Current	Milestone	Date						Spending	\$\$	
Time Line	DDC Phase i	4Q1998 2Q2000						Project-to-Date-Spending (thru '00)	45.6	
	Phase II	102001						2001 Current Projection (Plan)	°0.8	
	NDA Filing	102006						* See page 2 for detall.		
Projected Spending	2000	2001	2002	2003	2004	2005	Lotal			
by rear	6.6	9.0	37.0	29.0	23.0	15.0	119.6			
-						**				
(										
CONFIDENTIAL JH 008125			-			•				

TSP (ABT-510)

) .Ī

Total   Enrolled   Start   End   Cost   Start   Star	Total   Enrolled   19   19   19   19   19   19   19   1	Total   Enrolled   15   20   20   20   20   20   20   20   2	Columbia
Enrolled	Enrolled Start End Cost 38 Apr-2000 Sep-2001 S700 Jun-2001 Nov-2001 \$192 \$25.552	Total Enrolled Sep-2000 Sep-2000 Sep-2000 Sep-2000 Sep-2000 Sep-2001 Stroth Str	Total Enrolled ** 2000 AGU 20  Patients as of 8/00 Sep-2000 Sep-2001 S700  40 Jun-2001 Nov-2001 S3309  \$151 S960  \$192  \$2.552  \$2.000 AGU 3  \$18
Enrolled ** Start End Cost  38 Apr-2000 Sep-2000 \$240  Jun-2001 Nov-2001 \$309  \$151  \$252	Enrolled -3	Total Enrolled Saries End Cost Cost Saries State	Total Enrolled *** Start End Cost Cost 38 38 4 Apr-2000 Sep-2000 \$5240 \$700 \$40 Jun-2001 Nov-2001 \$151 \$580 \$51,202 \$2552
as of 8/00 Start End Cost 38 Apr-2000 Sep-2000 \$5240 Jun-2001 Nov-2001 \$309 5151 5252	as of 8/00         Start         End         Cost           38         Apr-2000         Sep-2000         \$240            Feb-2000         Sep-2001         \$700            Jun-2001         Nov-2001            \$3309         \$151         \$960           \$122         \$252	Patients   as of 8/00   Start   End   Cost     38   38   Apr-2000   Sep-2000   \$240     40     Feb-2000   Sep-2001   \$700     14     Jun-2001   Nov-2001       15     Jun-2001   Nov-2001       5309   5151   5800     5150   5252   5252     5200 AGU   \$1,202     52000 AGU   \$1,2	Patients   as of 8/00   Sep-2000   \$240     38
38 . ' Apr-2000 Sep-2000 \$240 Feb-2000 Sep-2001 \$700 Jun-2001 Nov-2001 \$3309 \$151 \$960 \$192	38 . ' Apr-2000 Sep-2000 \$240 Jun-2001 Nov-2001 \$700 Jun-2001 Nov-2001 \$700 \$309 \$151 \$960 \$122 \$2.552	38 38 4 Apr-2000 Sep-2001 \$700 40 Feb-2000 Sep-2001 \$700 114 Jun-2001 Nov-2001 \$3309 \$151 \$250 \$252 \$2500 AGU \$1,202 \$1,202 \$56	38 38 7 40 859-2000 \$540 40
Fcb-2000 Sep-2001 \$700 Jun-2001 Nov-2001 \$309 \$151 \$190 \$192	Feb-2000 Sep-2001 \$700 Jun-2001 Nov-2001 \$309 \$151 \$151 \$960 \$122 \$22.552	40 Feb-2000 Sep-2001 \$700  14 Jun-2001 Nov-2001 \$3309  \$151  \$2559  \$2762  \$1,808  \$1,202  \$568	40 Feb-2000 Sep-2001 \$700 14 Jun-2001 Nov-2001 \$3309 \$151 \$2520 \$2520 \$2762 \$276
Jun-2001 Nov-2001 \$309 \$151 \$150 \$190 \$190	Jun-2001 Nov-2001 \$3309 \$309 \$151 \$960 \$122 \$2.552	14 Jun-2001 Nov-2001 \$3309 \$151 \$151 \$960 \$1192 \$2.552 \$2.552 \$2.662 \$1,808 \$1,808 \$1,202 \$55	14 Jun-2001 Nov-2001 \$309 \$3151 \$151 \$960 \$1202 \$22559 \$2762 \$7762 \$1,808 \$1,202 \$1,202 \$58
		\$309 \$151 \$960 \$192 \$2,559 \$762 \$762 \$1,808 \$1,202 \$1,202 \$5 \$68	\$309 \$151 \$260 \$1122 \$2.552 \$762 \$762 \$1,808 \$1,808 \$1,202 \$5 \$5 \$68
		\$151 \$960 \$199 \$2,259 \$762 \$762 \$1,808 \$1,808 \$1,202 \$5 \$5	\$151 \$960 \$192 \$2.559 \$762 \$762 \$1,808 \$1,202 \$5 \$5 \$68 \$196
		\$960 \$192 \$2.552 \$2.652 \$762 \$762 \$1,808 \$1,808 \$1,202 \$5 \$5	\$960 \$192 \$2.552 \$000 AGU \$762 \$1,808 \$1,808 \$1,202 \$5 \$5 \$68 \$196
		\$1992 \$2,559 2000 AGU \$762 \$762 \$1,808 \$1,808 \$1,202 \$5 \$5	\$1992 \$2.559 2000 AGU \$762 \$762 \$1,808 \$1,808 \$1,202 \$5 \$5 \$68 \$196
		\$2.552 2000 AGU \$762 \$762 \$1,808 \$1,808 \$1,202 \$1,202 \$5 \$5	\$2.552 2000 AGU \$762 \$762 \$1,808 \$1,808 \$1,202 \$5 \$5 \$68 \$196
		2000 AGU \$762  \$762  2000 AGU \$1,808  \$1,808  \$1,202 \$5 \$5	2000 AGU \$762 \$762 2000 AGU \$1,808 2000 AGU \$1,202 \$5 \$5 \$68 \$196
		\$1,808 2000 AGU \$1,202 \$5 \$68	\$1,808 2000 AGU \$1,202 \$5 \$68 \$196
		\$1,202 \$1,202 \$5 \$68	\$1,202 \$1,202 \$5 \$68 \$196
		\$1,202 \$5 \$68	\$1,202 \$5 \$68 \$196
		\$\$ \$68	\$\$ \$68 \$16
		89\$	961\$
			9618

Ç

) [

ş

Therapoulic Area	Chesiogy	Con Con de do	Searcoad oak	pread colorec	lal and bladder	_			
Indications Description	Solid tumors such as lur Novel metalloproteinas - Cytostatic mechanism Oral dosing May prevent the growth	Solid tumors such as lung, ovarian, pandreas, preast, conduction and process.  Novel metalloproteinase inhibitor.  - Cytostatic mechanism.  - May prevent the growth of metastatic lesions and/or inhibit primary tumor gr.  - Superior efficacy or side-effect profile to competitive agents.	ian, pancreas, Nor. Lastalic lesions 1 profile to com	and/or inhibit p	creas, preast, connectar and braces.	rowth.			·
Gurrent Time Line	Milestone DDC DDC Phase II Phase III NDA Filing Launch	Date 102000 102001 302002 402005 202006				:	<u>ज्ञा द र •                                    </u>	Spending Project-to-Date-Spending (thru '00) 2001 Current Projection (Plan) . See page 2 for detail.	40.0 7.0°
Projected Spending by Year	5.0	2001	31.0	<b>2003</b> 35.0	200 <del>4</del> 26.0	wi o	<b>Total</b> 124.0		·

JH 008127

٤.

11

			7	2001 Plan De	2001 Plan Development Cost Summary	t Summary				_
ڪا	Program Status	1999	2000	2001	2002	2003	2004	2005	2006	
-{		9	01 02 03 04	91 92 93 94	1 Q1 Q2 Q3 Q4	01 02 03 04	01 02 03 04 01 02 03 04	01 02 03 04 01 02	1   Q2   Q4	
	Phase 1			=				<b>←</b>	<del>&lt;-</del>	
	Phase II						Control of the Contro		I annoh	
	Phase III		DDC							
احا	Major Development Activities and Costs	tivities and Co	sts	Total	Enrolled			2000 AGU	2001 Plan	
	Clinical Program			Patients	ns of 8/00	Start	End	Cost	Cost	
	Multiple Dose in Cancer Patients	Cancer Patients		40	:	10/01	10/02	\$300	\$769	
	ND Study			14	:	3Q/01	1Q/02	:	\$200	
	Other Shidies / EVR	:VR						i	\$108	
<u> </u>	Phase-1 Center / PK	PK	•					\$70	\$65	
	Variation Monday	T I I						\$778	\$754	
	Venius irtanaga	mont.			•			\$57	\$118	_
	Data Management Statistics	ill Statistics						\$1.205	\$2,314	_
	Chemistry, Manusacturing, and Controls (CMC)	uring, and Cont	rols (CMC)					2000 AGU	2001 Plan	
	Formulation / Analytical	nalytical						\$546	11,031	
								1.00	- Id :000	Т
	Drug Safety Support				•			2000 AGO	IIIII TAAT	
	Ongoing Drug Safety support	Safety support						\$1,681	\$2,125	
	Other Support Costs								6	
	L Discovery							21,447	845,14	
	Medical Affairs	80						\$2	\$20	
С		Regulatory Affairs / Research Quality Assurance	nality Assurance					\$26	\$39	
ON		nsing Fees	•		-			06\$	\$123	
FIL	Total Program	E1						\$5.000	27.000	$\neg$
)E										

IH 008128

C

Anti-Mitotic (ABT-751) Annual Development Plan Exhibit 1.6

Therapoulic Area Indications	Oncology Solid fumors	Oncology Solid tumors such as breast, lung, colorectal, and ovarian	ung, colorectal,	and ovarian						
Description	- Novel oral c	<ul> <li>Novel oral cytoloxic agent that inhibits tumor growth by inhibitit</li> <li>May be effective in pallents resistant to other cytoloxic agents</li> </ul>	resistant to oth	or growth by intersection	sibiting the poly ents	merization of tu	bulin, similar	<ul> <li>Novel oral cytoloxic agent that inhibits tumor growth by inhibiting the polymerization of tubulin, similar to the MOA of taxanes</li> <li>May be effective in patients resistant to other cytoloxic agents</li> </ul>		
Current	Milestone	Date				, ,		Spending	22	
Time Line	In-License Phase I	202000 10/2001				٠ .		Project-to-Date-Spending (thru '00)	6.0	
	Phase III	40/2001						2001 Current Projection (PLAN)	10.0*	
	Launch	10/2006						* See page 2 for detail.	]	
						r		`		
Projected Spending	2000	2001	2002	2003	Z004	2005	Ĭoiai			
Dy Year	6.0	10.0	27.0	35.0	25.0	12.0	115.0			
(										
CONFIDENTIAL JH 008129										

Anti-Mitotic (ABT-751)

Oil   1979   Oil		-		2001 Plan Development Cost Summary	Cost Summar	2003	7000	
Total Enrolled   Start   End   Cost	Program Status	Q2 Q3 Q4 Q1	2000 Q4 Q1 Q2 Q3	60, 20 10 01 05 03	ō	4 Q1 Q2 Q3 Q4	Q2 Q3	
Total Enrolled   2000 AGU   2   Pattents   as of 8/31/00   Start   End   Cost     24	Phase I Phase II Phase III		In-license					
Total Enrolled   Fullents   Ful	r Development A	ctivities and Costs		. 1 .				
Order In Cancer Patients #1 1 24         As of #811/00         Start is an of #81 is an of #811/00         End         Cost           Oses in Cancer Patients #1 2 24          Apr-2001         Nov-2001            Selficacy #1-#6         180          Aug-2001         Oct-2002            Selficacy #1-#6         180          Aug-2001         Oct-2002            sies / EVR          Aug-2001         Oct-2002             same agement          Aug-2001         Oct-2002             same agement of gament          Aug-2001         Oct-2002             same agement of gament of gamen			Total	Enrolled :			2000 AGU	2001 Plan
24 Jan-2001 Nov-2001 24 180 Apr-2001 Adv-2002	Clinical Program		Patients	ns of 8/31/00	Start	End	Cost	Cost
24 Apr-2001 May-2002  180 Aug-2001 Oct-2002	Multiple Dose in	n Cancer Patients #1	24	•	Jan-2001	Nov-2001	:	\$600
180 Aug-2001 Oct-2002	Multiple Dose in	n Cancer Patients #2	24	:	Apr-2001	May-2002	:	\$466
C) 2000 AGU	Safety and Effic	acy #1-#6	180	:	Aug-2001	Oct-2002	:	\$1,092
2000 AGU	Other Studies /	EVR					:	1
C.) 2000 AGU	Venture Manage	ement					:	\$2,762
C) 2000 AGU 20	Data Manageme	ent/Statistics					1	\$413
C) 2000 AGU 2000 AGU	ı						1	\$5,333
Analytical          Safety support.          rs          fairs / Research Quality Assurance          snsing Fees       \$6.000         Total Program       \$56.000	istry, Manufact	uring, and Controls (C)	MC)				2000 AGU	2001 Plan
Safety support.  Safety support.   In the search Quality Assurance  Total Program  Total Program  2000 AGU   2000 AGU    2000 AGU      \$6.000	Formulation / A	ınalytical					:	\$2,300
Safety support.  Safety support.  Total Program  Safety support.  2000 AGU     2000 AGU      \$6.000	Safety Support						2000 AGU	2001 Plan
15 in in in its fees in its Assurance in its Fees in i	Ongoing Drug	Safety support.					ŧ	\$1,685
irs / Research Quality Assurance sing Fees Total Program	r Support Costs				1		2000 AGU	2001 Plan
ins / Research Quality Assurance sing Fees Total Program	Discovery						:	\$26
000°9\$	Medical Affair	v		•			I	:
<u>000</u> .224	Regulatory Aff	airs / Research Quality Ass	urance				:	\$301
000'98	Other / In-Lice	nsing Fees					26.000	\$355
		Total Program					26,000	210,000

C

ĺ

) g

FTI (ABT-xxx)
Annual Development Plan
Exhibit 1.6

Therapeutic Area Indications	Oncology Solid lumors s	Oncology Solid tumors such as lung, breast, ovary, bladder and pancreas.	ast, ovary, blac	der and pancre	383.				П
Description	- Faresyltranse - Mechanism o	erase Inhibitor. of action is unkn	own, bul (houg	ht to inhibit fam	esylated prote	ins which are	- Faresylfranserase Inhibitor. - Mechanism of action is unknown, but thought to inhibit farnesylated proteins which are integral for malignant tumor growth.		
Gurrent Time Line	Milestones DDC Phase II Phase III NDA Filing Launch	Date 10/2001 40/2001 20/2003 30/2004 40/2006 40/2007	•				Spending Project-to-Date-Spending (thru '00) 36 2001 Current Projection (Plan) 6. See page 2 for detail.	35.0 6.0°	
Projected Spending	2000	2001	2002	2003	2004	2005	Total		
	N/A	6.0	15.0	30.0	30.0	. 18.0	0.86		
CON									
IFIDENTIAL H 008131	·						·		

ONCOLOGY - FTI ABT-xxx

			2001 Plan De	2001 Plan Development Cost Summary	t Summary			
Phase II   DDC   Phase III   Phase III   Phase III   DDC   Phase III   Phase III   PDC   Phase III		_	2002	2003	2004	ſ	20	ÕL
Particular   Par	_1	03	01 02 03	01   02   03	Q1 Q2 Q3	Q2 Q3	Q1 Q2	_
Part	Phase I				ASCULPTURE LINES		<del>(</del>	<del>(</del>
Total   Start   End   Cost	Phase II Phase III	DDC		WENTERN LINE			MINISTER NDA	Launch
Patients   Enrolled   Start   End   Cost	r Development Activities ar	nd Costs	Total				2000 AGU	2001 Plan
N/A	cal Program		Patients	Enrolled	Start	End	Cost	Cost
N/A	Phase I Multiple Escalating	Dose	. 40		Dec-2001	Nov-2002	N/A	\$150
N/A  N/A  (CMC)  (CMC)		٠		٠,			N/A	:
N/A   1000 AGU   2000 AGU   200	Fhase-1 Center						N/A	\$328
(CMC) 2000 AGU 2000 AGU N/A	Veniure Ivianagement	E		-,			N/A	2100
(CMC) 2000 AGU N/A.  N/A.  2000 AGU N/A  1 1 2000 AGU N/A	Data Managemenyotatistici	a					AM MA	\$578
N/A  2000 AGU  N/A  N/A  N/A  N/A  N/A  N/A  N/A  N/	nietw Manufacturing and						2000 AGU	2001 Plan
2000 AGU N/A  Pport.  1	Formulation / Analytical						N/A.	\$1,100
N/A   1   1   2000 AGU   N/A   N/A							2000 AGU	2001 Plan
2000 AGU  N/A  Safetire / Research Quality Assurance  In-licensing Fees  M/A  N/A  N/A  M/A  AMA  AMA	g Safety Support Drug Safety support.			`;5-			N/A	\$2,184
Is N/A N/A N/A N/A Fairs / Research Quality Assurance N/A	27.70			. , 47			2000 AGU	2001 Plan
Discovery Medical Affairs Medical Affairs Regulatory Affairs / Research Quality Assurance N/A Other Costs / In-licensing Fees Total Program	er support Cosis			2			N/A	\$2,000
NA Regulatory Affairs / Research Quality Assurance  Other Costs / In-licensing Fees  Total Program	Discovery			,			N/A	i
N/A   N/	•						N/A	:
Total Program		aren Quanty Assurance	•				N/A	\$138
							NA	26.000
	L							

Ç į

Į

Í

Dopamine Receptor Agonist (ABT-xxx)
Annual Development Plan
Exhibit 1.6

Therapeutic Area indications	Other Male Erectile C	Olher Male Erecille Dysfunction (MED)	6						
Description	D4 Dopamine Reception     Targets D4 receptors in     Additionally this approafor MED.	e Receptor Agonist. ecaptors in the brain his approach offers	nist. orain which offers opportunity	srs the potential / for compound	I for efficacy in s with improve	patients with N	<ul> <li>- D4 Doparnine Receptor Agonist.</li> <li>- Targets D4 receptors in the brain which offers the potential for efficacy in patients with MED that do not respond to Vlagra.</li> <li>- Additionally this approach offers opportunity for compounds with improved tolerability relative to other Doparnine agents that are clinically used for MED.</li> </ul>	pesn.	
Current Time Line	Milestones	Date 40/2001				Δ)I	Spending	×	
	Phase I	20/2002					Project-to-Date-Spending (thru '00)	35.0	
	Phase III	10/2005					2001 Current Projection (Plan)	6.0	
	Launch	40/2007				50 F 5	• See page 2 for detail.		
									•
Projected Spending	2000	2001	2002	2002	2004	2005	Iqial		
	N/A	6.0	15.0	30.0	30.0	18.0	0.86		
								-	
DENTIAL 008133									

(

11 -

Dopamine Receptor Aganist ABT-xxx

Pharmaceutical Products Division Sample Direct/Indirect Project Funding Distribution 2001 Plan (5000)

( i

; **{** 

• 1

) {

**»** 1

1:

Direct	Indirect	Total	Direct	Indirect	Total
0.3	0.0	0.4	ı	•	•
4.8	1.6	6.5	0.8	0.2	6.0
2.2	0.2	2.4	Ξ	0.3	1.3
1.6	0.2	1.7	. 1.8	0.3	2.1
4.8	0.4	5.3	0.8	0.2	1.0
2.0	0.1	2.1	0.1	0.0	0.1
4.2	0.5	4.6	0.1	0.0	0.1
0.2	0.0	0.3	0.0	0.0	0.0
0.8	0.1	0.0	0.0	0.0	0.0
9.1	•	9.1	0.1	•	0.1
0.7	•	0.7	,		•
15.0	ı	15.0	•	•	•
43.1	•	43.1	1.3	•	1.3
81.4	3.2	84.6	6.2	6.0	7.1
96.2%	3.8%	100.0%	86.6%	13.4%	100.0%

# Pharmaceutical Products Division Sample Direct/Indirect Rate & Headcount Distribution 2001 Plan

į

Rate:	Data Management	· <u>1</u>	Toxicology/Pathology	
Direct	( 577		5,277	
Payroll (Both PMP and Supv/Mgr)	6,577 53		51	
Office Supplies	26		84	
T&E			73	
Sem/Edu	21		440	
Supplies	41		67	
Consultant	291		4	
Printing	73		***	
Clinical Tracking Costs	4,075		258	
Depreciation	1,031		921	
UNIX Based Support	3,453			
Utilities	62		1,479	
Floorspace	579		1,777	
Housekeeping	23		389	
Other	112	A	9,042	
Sub-Total Direct	16,416		, _ ,,042	
	-			
Indirect			388	
Patents & Trademarks	285		949	
Corporate Indirect	697		458	
PPD Indirect (Mgmt.)	337		584	
Department Overhead	396		62	
Other	46			
Sub-Total Indirect	1,761		2,441	
340 1041111111111				
	18,177		11,483	
Total		•		
% Direct	90%		. 79%	
% Indirect	10%		21%	
Headcount:			•	
The sea III and an unit	123	88%		88%
Direct Headcount	17	12%	7	12%
Indirect Headcount	••			
Total Headcount	140	:	60	
	92.06		135.42	
Rate	1,600		1,600	
Hours	147,296		216,672	
Annual Rate	147,230		·	

 $\mathsf{C}$ į

Ę

1

) I

**y** 1

-37-

#### EXHIBIT 1.17

### EISAI TERRITORY

Italy, co-exclusive rights with Abbott, unless Abbott exercises its rights under the

terms of the Eisai Agreement to take an exclusive right to Italy.

1.	Bhutan
2.	Brunei
3.	Cambodia
4.	People's Republic of China
5.	Republic of China (Taiwan)
6.	India
7.	Indonesia
8.	Japan Strang (North Korea)
9.	Democratic People's Republic of Korea (North Korea)
10.	Republic of Korea
11.	Laos
12.	Macao
13.	Malaysia
14.	Mongolia
15.	Myanmar
16.	Nepal ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( ) (
17.	Pakistan
18.	Papua New Guinea
19.	Philippines

Bhutan

Singapore

Sri Lanka

Thailand

Vietnam

20.

21.

22.

23. 24.

-38-

#### EXHIBIT 1.40

## PROGRAM COMPOUNDS

In-License Agreement	Program Compound	Development Phase
Taisho Wakunaga Eisai	ABT-627 (Endothelin antagonist) ABT-773 (Ketolide antibiotic) ABT-594 (Cholinergic channel modulator) ABT-492 (Quinolone antibiotic) ABT-751 (Antimitotic) ABT-510 (Thrombospondin peptide)	phase III phase III late phase II phase I phase I phase I phase I
Preclinical Programs:		
FTI Program ED Program	ABT-518 (Matrix metalloproteinase inhibitor)	late preclinical late preclinical phase I

CONFIDENTIAL JH 008138

Last printed 3/13/01 1:47 PM

1 [

. . . .

(

1:

-39-

## EXHIBIT 1.43

EXAMPLE OF PROGRAM RELATED COSTS FOR ONE PROGRAM COMPOUND

CONFIDENTIAL JH 008139

M:\Domestic\Pals & Adams\John Hancock\JH rfa FINAL.DOC

Last printed 3/13/01 1:47 PM

1:

) [

2001 KEY RATES	2001 % Change	Annual Annual Hourly Total Annual IIS Rate Hours Rate Rate Hours	380         204,154         135,42         1,600         216,672         11.4%         -4.8%         6.1%           500         231,600         141.64         1,650         233,706         -2.1%         3.1%         0.9%           768         204,381         116.88         1,850         216,228         1.1%         4.6%         5.8%           580         204,154         173.56         1,600         277,696         42.8%         -4.8%         36.0%	600 231,600 135.00 1,600 216,000 -6.7%6.7%6.7% 700 193,103 123.75 1,700 210,375 8.9% 8.9%	,800 195,372 116,71 1,800 210,078 7.5% 7.5%   600 257,280 162.11 1,600 259,376 0.8% 0.8%	,600 144,064 92.06 1,600 147,296 2.2% 2.2% ,800 175,950 99.10 1,800 178,380 1.4% 1.4%	,600 200,800 134.49 1,600 215,184 7.2% 7.2%	1,800 247,770 142.91 1,800 257,238 3.8% 3.8%
20	2000	Rate · Hours	121.52 1,680 144.75 1,600 115.60 1,768 121.52 1,680	144.75 1,600 113.59 1,700	108.54 1,800 160.80 1,600	90.04 1,600 97.75 1,800	125.50 1,600	137.65 1,800
			DRUG SAFETY Toxicology/Pathology - PMP/TMP Metabolism/Microscopy - PMP/TMP Comparative Medicine - PMP/TMP Strategic & Exploratory - PMP/TMP	PHASE I CENTER Pharmacokinetics 4PK -PMP/TMP Clin. Res. MDs 42P - PMP Clin Res. Spec. 420-PMP/TMP	PARD. Prod Dev - PMP, TMP IDS - PMP, TMP	DEV OPERATIONS Data Mgmt D433 - TMP/PMP Stats - PMP/TMP	RAIQA RAIQA - PMP & TMP	DISCOVERY

-40-

#### EXHIBIT 9.2

## PAYMENT INSTRUCTIONS

Fleet Boston
ABA No. 011000390
Boston, Massachusetts 02110
Account of: John Hancock Life Insurance Co. Private Placement Collection Acct.
Account Number: 541-55417
On Order of: Abbott Laboratories -- Research Funding Agreement dated as of March 13, 2001

E-3233160

. 1

) {

C

· [

) E

-41-

### Exhibit 12.2(d)

### Further Information Regarding Program Compounds

COMPOUND	CHEMICAL NAME	CURRENT STAGE OF DEVELOPMENT
ABT-627 Endothelin antagonist	(2R,3R,4S)-4-(1,3-benzodioxol-5- yl)-1-[2-(dibutylamino)-2- oxoethyl]-2-(4-methoxyphenyl)-3- pyrrolidinecarboxylic acid	Phase III
ABT-773 Ketolide antibiotic	(3aS,4R,7R,9R,10R,11S,13R,15R,15R,15aR)-4-ethyl-3a,7,9,11,13,15-hexamethyl-2,6,8,14-tetraoxo-11-{[(2E)-3-(3-quinolinyl)-2-propenyl]oxy}tetradecahydro-2H-oxacyclotetradecino[4,3-d][1,3]oxazol-10-yl 3,4,6-trideoxy-3-(dimethylamino)—D-xylo-hexopyranoside	Phase III
ABT-594 Cholinergic channel modulator	(2R)-azetidinylmethyl 6-chloro-3- pyridinyl ether hydrochloride	Phase II
ABT-492 Quinoline Antibiotic	potassium 1-(6-amino-3,5-difluoro-2-pyridinyl)-8-chloro-6-fluoro-7-(3-hydroxy-1-azetidinyl)-4-oxo-1,4-dihydro-3-quinolinecarboxylate	Phase I
ABT-518  Matrix metalloproteinase inhibitor	(1S)-1-[(4S)-2,2-dimethyl-1,3- dioxolan-4-yl]-2-({4-[4- (trifluoromethoxy)phenoxy]phenyl} sulfonyl)ethyl(hydroxy)formamide	Phase I
ABT-751 Antimitotic	N-[2-(4-hydroxyanilino)-3- pyridinyi]-4- methoxybenzenesulfonamide	Phase I
Farnesyltransferase inhibitor Dopamine Receptor Agonist for Erectile Dysfunction	N.A.	Pre-Clinical Program Pre-Clinical Program

(

**)** į

-42-

#### EXHIBIT 12.2(e)

### Certain Patent Information

#### ABT-627

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
Australia	08/04/1995	711832	Issued	08/04/2015
Brazil	02/12/1997		Pending .	
Canada	08/04/1995		Pending	
EP*	08/04/1995		Pending	
Hong Kong	07/15/1998		Pending	
Israel	08/10/1995		Pending	
Japan	08/04/1995		Pending	
Korea	08/04/1995		Pending	
Mexico	08/04/1995	_	Pending	
Philippines	08/17/1995		Pending	
USA	05/30/1995	5,767,144	Issued	06/16/2015

<sup>\*</sup>Europe: Austria, Belgium, Great Britain, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland

-43-

## Exhibit 12.2(e) (Cont'd)

### ABT-773 (Subject to Taisho Agreement)

COUNTRY	FILING DATE .	PATENT NUMBER	STATUS	EXP. DATE
Argentina	09/03/1997	·	Pending	
Australia	09/02/1997		Pending	
Brazil	05/13/1997		Pending	
Brazil	09/02/1997		Pending	
Bulgaria	09/02/1997		Pending	
Belarus	09/02/1997		Pending	
China	09/02/1997		Pending	
Chile	09/04/1997		Pending	
Canada	09/02/1997		Pending	
Columbia	09/02/1997		Pending	
Czech Republic	09/02/1997		Pending	
EP*	09/02/1997		Pending	
	08/29/1997		Pending	
Guatemala	09/02/1997	<del></del>	Pending	
Hong Kong	09/03/1997		Pending	
Croatia .	09/03/1997		Pending	
Hungary	09/04/1997		Pending	
Indonesia			Pending	
India	Pending-Black Box			
Israel	09/02/1997		Pending	
	09/02/1997		Pending	
Japan Korea	09/02/1997		Pending	
	09/02/1997		Pending	
Mexico	08/26/1997		Pending	
Malaysia	09/02/1997	_	Pending	
Norway	03/02/133/			

CONFIDENTIAL JH 008144

) E

(

) ;

) [

-44-

## Exhibit 12.2(e) (cont'd)

#### ABT-773 (cont'd) (Subject to Taisho Agreement)

COUNTRY	OUNTRY FILING DATE		STATUS	EXP. DATE
New Zealand	09/02/1997	NUMBER	Pending	
Philippines	09/02/1997		Pending	
	10/13/1997	136010	Issued .	10/13/2013
Pakistan	09/02/1997		Pending	
Poland			Pending	
Romania	09/02/1997		Pending	
Russia	09/02/1997	1	Issued	08/20/2017
South Africa	08/20/1997	97/7474		
Singapore	09/02/1997		Pending	
Slovak Republic	09/02/1997		Pending	09/02/2017
Slovenia	09/02/1997	20023	Issued	09/02/2017
Saudi Arabia	02/10/1998		Pending	
Thailand	09/03/1997		Pending	
Turkey	09/02/1997	TR 01127 B	issued	09/02/2017
Taiwan	09/05/1997		Pending	
	09/02/1997	-	Pending	
UA .		5,866,549	Issued	09/04/2016
USA	07/03/1997	3,000.040	Pending	
Yugoslavia	09/02/1997			Carro Ireland Italy

\*Europe: Austria, Belgium, Great Britain, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland

-45-

### EXHIBIT 12.2(e) (Cont'd)

### ABT-594

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
Australia	10/08/1993	687017	Issued	10/18/2013
Brazil	04/30/1997		Pending	
Canada	10/08/1993		Pending	
EP*	10/08/1993		Pending	
Hong Kong	12/10/1998		Pending	
Israel	10/04/1993	107184	Issued	10/04/2013
	10/08/1993	3098035	Issued	10/08/2013
Japan Korea	10/08/1993		Pending	
Mexico	10/08/1993		Pending	
	10/07/1993		Pending	
Philippines	06/07/1995	5,948,793	Issued	09/07/2016
USA	100/07/1000	1 -11-		C Indeed Italy

<sup>\*</sup>Europe: Austria, Belgium, Great Britain, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland

C

-46-

#### EXHIBIT 12.2(e) (Cont'd)

#### ABT-492

(Subject to Wakunaga Agreement)

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
Australia	09/24/1999		Pending	.,
Brazil	11/29/1999		Pending	
Canada	12/06/1999		Pending	
China	10/22/1999	1258674A	Issued	
Hong Kong				
EP*	12/08/1999	0992501	Issued	
Hungary	11/23/1999	9904389	Issued	
Republic of Korea	08/29/2000			
Mexico	10/14/1999		Pending	
Russian Federation	05/26/2000		Pending	
USA	06/10/1999		Pending	
Japan	10/06/1999	2000-136191	Issued	

\*Europe: Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, Great Britain, Greece, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, Sweden

### EXHIBIT 12.2(e) (Cont'd)

#### ABT-510

COUNTRY	FILING DATE	PATENT STATUS NUMBER Pending		EXP. DATE
Argentina	05/21/1999			
Australia	05/21/1999		Filing in Process	
Brazil	05/21/1999		Filing in Process	<u> </u>
Bulgaria	05/21/1999		Filing in Process	ļ
China	05/21/1999		Filing in Process	
Chile	05/20/1999		Pending	
Canada	05/21/1999		Filing in Process	<u> </u>
Columbia	05/21/1999		Pending	
Czech Republic	05/21/1999		Filing in Process	<u> </u>
EP*	05/21/1999		Filing in Process	
Hong Kong	05/21/1999		Filing in Process	
Hungary	05/21/1999		Pending	
India	05/21/1999		Filing in Process	
Israel	05/21/1999		Filing in Process	
Japan .	05/21/1999		Filing in Process	
Korea	05/21/1999		I ming in 1 10ccss	
Mexico	05/21/1999		Filing in Process	
Norway .	05/21/1999		Filing in Process	
New Zealand	05/21/1999		Filing in Process	
Philippines	05/21/1999		Pending	
Poland	05/21/1999		Filing in Process	
South Africa	05/21/1999		Filing in Process	
Slovak Republic	05/21/1999		Filing in Process	
Saudi Arabia	05/21/1999		Pending	
Turkey	05/21/1999		Filing in Process	
Taiwan	05/21/1999		Pending	
USA	05/21/1999		Pending	Germany Greec

<sup>\*</sup>Europe: Austria, Belgium, Great Britain, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland

CONFIDENTIAL JH 008148

**)** [

**)** {

-48-

### EXHIBIT 12.2(e) (Cont'd)

#### ABT-518

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
Argentina	07/30/1998		Pending	
Australia	07/27/1998		Pending	<u> </u>
Brazil	07/27/1998		Pending	
Bulgaria	07/27/1998		Pending	
China	07/27/1998		Pending	
Chile	07/17/1998		Pending	
Canada	07/27/1998		Pending	
Columbia	07/29/1998		Pending	
Czech Republic	07/27/1998		Pending	
EP*	07/27/1998		Pending	
Hungary	07/27/1998		Pending	
Israel	07/27/1998		Pending	
Japan	07/27/1998		Pending	
Korea	07/27/1998		Pending	
Mexico	07/27/1998		Pending	
Norway	07/27/1998		Pending	1
New Zealand	07/27/1998		Pending	
Philippines	07/27/1998		Pending	
Poland	07/27/1998		Pending	
South Africa	07/30/1998	98/6828	Issued	07/30/2018
Slovak Republic	07/27/1998		Pending	
Saudi Arabia	12/15/1998		Pending	
Turkey	07/27/1998		Pending	
Taiwan	07/31/1998		Pending	
USA	08/05/1998		Pending	Freece Ireland Italy.

<sup>\*</sup>Europe: Austria, Belgium, Great Britain, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland

CONFIDENTIAL JH 008149

) [

-49-

#### EXHIBIT 12.2(e) (Cont'd)

## ABT-751 (Subject to Eisai Agreement)

	FILING DATE	PATENT	STATUS	EXP. DATE
COUNTRY	FILING DATE	1	1	
		NUMBER		
<u> </u>	08/08/1991	5,250,549	Issued	08/08/2011
USA.	08/08/1951	1	}	08/08/2011
1		5,292,758		
0	I 08/07/1991	EP 472,053	Issued	08/07/2011
Germany		EP 472.053	Issued	08/07/2011
United Kingdom	08/07/1991			08/07/2011
Erance	08/07/1991	EP 472,053	Issued	1 08/07/2011

CONFIDENTIAL JH 008150

Last printed 3/13/01 1:47 PM

**)** [

C

-50-

#### EXHIBIT 12.2(f)

#### COMMUNICATIONS

With respect to ABT-594, Abbott has received the following communications:

- Correspondence from Sibia Neurosciences, 505 Coast Blvd. South, Suite 300, La Jolla, CA 92037 (Sibia was acquired by Merck & Co., Inc. in August, 1999) including, most recently, a letter dated March 13, 1998.
- Correspondence from ICT Pharmaceuticals c/o Stadheim and Grear, Ltd., 400 North Michigan Ave., Chicago, IL 60611 including, most recently, a letter dated September 14, 2000.

The Sibia and ICT correspondence each refer to their patents on research tools.

(

٠ ٤

**! !** 

-51-

EXHIBIT 12.2(i)

Compound Reports

CONFIDENTIAL

ABT - 773

## **Descriptive Memorandum**

February 2001

**Abbott Laboratories** 

CONFIDENTIAL JH 008153

1 1

#### ABT-773

(

1

**)** {

#### Opportunity Overview

ABT-773 pertains to a promising new class of antibiotics known as ketolides. ABT-773 is likely to have activity against resistant strains of bacteria and will, therefore, compete effectively against currently marketed antibiotics. The compound is currently in Phase II/III trials. Phase III clinical trials began in Q4, 2000. ABT-773 has an expected U.S. launch date in Q1, 2004. Ex-U.S. launches are projected in 2004 for Europe and Japan.

Product features such as high efficacy, activity against resistant strains of bacteria and convenience should enable it to compete against both Zithromax and newer agents such as the quinolones. Dosing is expected to be once-a-day. A 5-day convenience pak at a competitive price will help maximize sales.

The US Market

The overall antibiotic market in the U.S. reached \$8.9 billion in sales in 1999. The tab/cap segment is the largest; sales in 1999 were \$5.7 billion. The I.V. and oral suspension segments are comparatively smaller; total sales topped \$2.1 and \$1.1 billion, respectively.

Tab/cap and oral suspension prescription volume had been declining 1-2% per year in the period of 1995-1998, due to more appropriate prescribing in the face of increasing resistance. However, total tab/cap prescription volume recovered in 1999 and grew 6.3%. Even in the face of negative pressure on antibiotic use, dollar sales in the U.S. have continued to increase, particularly in the tab/cap market. This is due to the trend of replacing relatively low-cost generic agents with higher priced premium antibiotics. The market is willing to bear higher costs for agents that satisfy unmet needs. The I.V. market has grown splightly in terms of sales, also being driven largely by the replacement of generic agents with more costly branded agents.

Macrolides, largely fueled by the gains of Zithromax, have seen significant growth in terms of both prescriptions and sales. Zithromax prescriptions far outnumber those of other competitors, while its sales have nearly surpassed those of the sales leader, Cipro. Historically, quinolones saw relatively limited use for community respiratory tract infections (RTIs) because of poor Gram-positive coverage and sub-optimal adverse event profiles. Newer quinolones such as Levaquin have been successful in achieving more widespread use by virtue of its improved activity and adverse event profile. Levaquin currently accounts for approximately 30% of the quinolone market share. It is anticipated that recent quinolone introductions (Avelox, Tequin) will build upon the RTI momentum established by Levaquin. The growth of the macrolide and quinolone classes has come largely at the expense of cephalosporins and generic agents such as erythromycin and penicillin.

The following table shows 1999 tab/cap sales and prescriptions by class/product:

		Sales		TRXs			
	Dalas (SMA)	Share	CAGReses	TRXs (MM)	Share	CAGR <sub>95-99</sub>	
	Sales (\$MM)			52.5	23.7%	-5.6%	
Penicillins	\$148.3	2.6%	-1.0%		17.1%	-3.5%	
Cephalosporins	\$980.9	17.2%	-5.8%	37.9	2.3%	-1.0%	
Ceftin	\$383.9	6.7%	1.8%	5.0		11.3%	
Cefzil	\$188.7	3.3%	12.5%	2.7	1.2%	-4.8%	
Other .	\$408.3	7.1%	-14.7%	30.1	13.6%		
Ext. Spec. Macrolides	\$1,595.6	27.9%	19.9%	36.1	16.3%	20.8%	
	\$690.5	12.1%	6.1%	11.3	5.1%	1.2%	
Biaxin ·		15.6%	42.1%	24.4	11.0%	41.5%	
Zithromax	\$891.1		21.0%	0.4	0.2%	53.0%	
Other	\$14.0	0.2%		24.0	10.8%	11.7%	
Quinolones	\$1,622.1	28.4%	17.0%		6.4%	5.1%	
Cipro	\$902.5	15.8%	8.3%	14.1	3.1%	NA	
Levaguin	\$529.4	9.3%	NA	7.0		-6.4%	
Other	\$190.2	3.3%	-2.2%	3.0	1.3%		
	5778.1	13.5%	17.8%	10.7	4.8%	11.8%	
Augmentin	\$590.5	10.3%	-1.1%	60.4	27.3%	-4.1%	
Other Classes TOTAL TAB/CAP	\$5,715.4	100.0%	8.9%	221.5	100.0%	0.1%	

ŧ

**)** {

33

#### U.S. Market Projections

Resistance to antibiotics is likely to increase, creating opportunities for new agents with activity against resistance. Physicians will be urged to choose agents with an appropriate spectrum of activity relative to the infection being treated. Resistance will increasingly become part of the promotional mix for emerging agents. The ability of an agent to treat resistant strains and the real or perceived ability to slow or prevent resistance development (mutation prevention concentration, low mutation frequency, structure-activity relationships, etc.) may confer competitive advantage to such agents.

- Quinolones, which historically have seen limited use in community-acquired respiratory infections, will become a significant class in this segment as new agents from this class are launched that specifically target RTIs.
- The market will become more competitive as new agents enter both the community segment (ketolides, quinolones) as well as the nosocomial segment (oxazolidinones, streptogramins, everninomycins, peptides, others).
- Several key branded antibiotics will lose patent exclusivity over the next three to five years.. This may
  create an opportunity in the pediatric market as the top three pediatric brands (Augmentin, Cefzil,
  Zithromax) are among those losing patent exclusivity.

Antiviral influenza and cold therapeutics, as well as an increasing number of antibacterial vaccines may have a negative impact on antibiotic prescriptions.

#### The Ex-U.S. Market

Ex-U.S. sales of antibiotics totaled \$11.7 billion in 1999. Tab/cap represents the largest segment, with sales of \$9.4 billion from 770 million total prescriptions. Total Rx growth has been flat, with a 1996-99 CAGR of 0.5%. The use of antibiotics is predicted to slowly decline due to more judicious use of antibacterials in the face of increasing bacterial resistance.

Ex-U.S., the quinolone class accounted for 8% of total tab/cap market prescriptions (62 million Rxs) and 13% of sales (\$1.2 billion). Ciprofloxacin is the market leader ex-U.S. with approximately 47% of the quinolone market Rxs (29 million Rxs) and 44% (\$530MM) of sales. Levofloxacin launched in many European markets in 1998/1999 and holds approximately 14% Rx share of the European quinolone market and 0.8% of the overall tab/cap market. Although grepafloxacin and trovafloxacin also launched in some European countries in 1999, both products were recently pulled from the market due to liver toxicity and other complications. Moxifloxacin launched in Germany in Q4 1999, but has not yet been approved in other markets. In Japan, levofloxacin launched in 1994 and still commands a 65% Rx share of the quinolone market and 10% of the Japanese tab/cap market overall. Japan accounts for approximately 80% of ex-U.S. levofloxacin sales (\$370MM).

#### Scientific Rationale for ABT-773

The likely profile of ABT-773 justifies further development

- ABT-773 pertains to a new class of antibiotics.
- Good activity against resistant Gram + organisms, particularly macrolide-resistant S. pneumoniae.
- Convenience, safety, and tolerability profile competitive with Z-pak.
- Oral Suspension and I.V. forms enabling penetration into pediatrics and hospital segments.

#### Clinical Studies

C

The safety and efficacy of ABT-773 in AECB were studied in a multi-center Phase II clinical trial conducted between January and April of 1999. Dosing regimens of 100mg TID and 200mg TID were tested. Of the 169 enrolled patients, 159 were clinically evaluable and 96 were both clinically and bacteriologically evaluable. The following chart summarizes the results.

Bacterial Eradication	ABT-773	ABT-773	Overall
	100mg TID	200mg TID	Eradication
S. pneumoniae	100% (13/13)	90% (9/10)	96% (22/23)
M. catarrhalis	100% (6/6)	100% (7/7)	100% (13/13)
H. influenzae	96% (23/24)	92% (24/26)	92% (47/50)
H. parainfluenzae	100% (6/6)	88% (7/8)	93% (13/14)

Clinical Response	ABT-773 100mg TID	ABT-773 200mg TID	
Cure	96% (77/80)	92% (73/79)	
Failure	4% (3/80)	8% (6/79)	

Clinical and Bacterial	ABT-773	ABT-773	
Response	100mg TID	200mg TID	
Cure	96% (46/48)	94% (45/48)	
Failure	4% (2/48)	6% (3/48)	

	ABT-773	ABT-773	Overall
Adverse Events	100mg TID	200mg TID	
Taste Perversion	5% (4/84)	8% (7/85)	6.5% (11/169)
Diarrhea	11% (9/84)	6% (5/8 <i>5</i> )	8% (14/169)
Nausea	2% (2/84)	2% (2/85)	2% (4/169)
Abdominal Pain	1% (1/84)	2% (2/85)	2% (3/169)
Headache	2% (2/84)	1% (1/85)	2% (3/169)
Rash	2% (2/84)	1% (1/85)	2% (3/169)
Dyspnea	2% (2/84)		1% (2/169)
Elev. Liver Funct. Test	1% (1/84)	1% (1/85)	1% (2/169)
Fever		2% (2/85)	1% (2/169)

P's Exhibit 32 Part 4

ì

Abdominal Pain

The safety and efficacy of ABT-773 in AECB were studied in a multi-center Phase IIb clinical trial from October 1999 to March 2000. Doses of 150mg QD, 300mg QD, and 600mg QD were tested. Of the enrolled subjects, 342 were clinically evaluable, and 169 were both clinically and bacteriologically evaluable. The following chart summarizes the results.

Bacterial Eradication	AB	T-773 ng QD		3T-773 mg QD		T-773 mg QD	Overall	Eradication
S.pneumoniae M.catarrhalis H. influenzae	83% 80% 94%	(10/12) (8/10) (17/16)	90% 92% 89%	(9/10) (12/13) (17/19)	100% 91% 83%	(13/13) (10/11) (19/23)	91% 88% 88%	(32/35) (30/34) (53/60)
Clinical Response Cure Failure	87% 13%	(98/113) (15/113)	90% 10%	(105/117) (12/117)	90% 10%	(101/112) (11/112)		
Clinical & Bacteriol Cure	ogical R 84%	esponse (42/50)	88%	(49/56)	94%	(59/63)		
Failure	16%	(8/50)	12%	(7/56)	6%	(4/63)		
Adverse Events Taste Perversion Diarrhea Nausea Vomiting Nausea & Vomiting	5% 13% 7% 2%	: <b></b>	19% 12% 13% 3% <1%	(15/129) (17/129) (4/1229) (1/129)	29% 21% 30% 11% 4% 4%	(37/129) (27/129) (38/129) (14/129) (5/129) (5/129)	17% 15% 17% 5% 2% 4%	(66/384) (58/384) (64/384) (21/384) (6/384) (15/384)

The safety and efficacy of ABT-773 in Acute Bacterial Sinusitis (ABS) were studied in a multi-center Phase IIb clinical trial conducted from October 1999 to March 2000. Dosing regimens of 150mg QD, 300mg QD, and 600mg QD were tested. Of the 292 enrolled subjects, 246 were clinically evaluable. The following chart summarizes the results.

Bacterial Eradication		BT-773 Omg QD		B T-773 0mg QD		BT-773 Omg QD		Overall adication
S.pneumonia M. catarrhalis H. influenzae S.aureus		3/3 8/9 3/5 1/1		8/8 3/4 7/7 1/1		9/12 4/4 5/7 3/4		20/23 15/17 15/19 5/6
Clinical Response Cure Failure	89% 11%	(70/79) (9/79)	83% 17%	(70/84) (14/84)	71% 29%	(59/83) (24/83)		
Adverse Events Taste Perversion Diarrhea Nausea Vomiting	1% 6% 3% 1%	16/97) (6/97) (3/97) (1/97)	14% 6% 12% 6%	(14/98) (6/98) (12/98) (6/98)	27% 17% 26% 17%	(26/97) (16/97) (25/97) (16/97)	14% 10% 14% 8%	(41/292) (28/292) (40/292) (23/292)

The safety and efficacy of ABT-773 in community-acquired pneumonia (CAP) were studied in a multi-center Phase IIb clinical trial from October 1999 to March 2000. Dosing regimens of 300mg QD and 600mg QD were tested. Of the 187 enrolled subjects, 1248 were clinically evaluable, and 15 were both clinically and bacteriologically evaluable. The following chart summarizes the results.

Bacterial Eradication	ABT-77 300mg		ABT-77 600mg		Overal Eradica	
S. pneumoniae M. catarrhalis H. influenzae M. pṇeumoniae C. pneumoniae L pneumoniae	87% 75% 100% 93% 95% 100%	(13/15) (6/8) (9/9) (13/14) (19/20) (3/3)	100% 50% 72% 93% 79% 100%	(7/7) (2/4) (13/18) (14/15) (19/24) (2/2)	91% 67% 81% 93% 86% 100%	(20/22) (8/12) (22/27) (27/29) (38/144) (5/5)
Clinical Response Cure Failure	92% 8%	(72/78) (6/78)	80% 20%	(56/70) (14/70)		
Clinical & Bacteria Cure Failure	al Respon 92% 8%	(54/59) (5/59)	82% 18%	(47/57) (10/57)		
Adverse Events Taste Perversion Diarrhea Nausea V omitting	17% 14% 12% 10%	(16/95) (13/95) (11/95) (9/95)	26% 19% 22% 15%	(24/92) (17/92) (20/92) (14/92)	 21% 16% 17% 12%	(40/187) (30/187) (31/187) (23/187)

#### Appendix 1

#### **Key Emerging Competitors**

		Company	Class	Status
Generic	Brand		Quinolone	Approved by FDA
moxifloxacin	Avelox	Bayer	Quiloione	12/13/00
		546	Quinolone	Approved by FDA
gatifloxacin	Tequin	BMS	Quinoions	12/21/00
		SKB	Quinolone	Filed NDA 12/15
gemifloxacin	Factive		Quinolone	Phase I
T-3811	TBD	BMS/Toyama		Filed NDA 3/00
	Ketek	Aventis	Ketolide	
telithromycin			Oxazolidinone	Approved by FDA
linezolid	Zyvox	Pharmacia	Oxazonaniono	Q2 '00

C

11

CONFIDENTIAL

ABT - 627

## **Descriptive Memorandum**

February 2001

**Abbott Laboratories** 

#### ABT-627

C

**b f** 

#### Opportunity Overview

ABT-627 is an orally bioavailable endothelin antagonist with a high selectivity for the Eta receptor. The endothelins (ET-1, ET-2, ET-3) are a family of 21 amino acid peptides first identified in 1988. Endothelin is a potent, long acting vasoconstrictor produced by vascular endothelial cells. The known biological effect of ET-1 are believed to be mediated principally through the Eta receptor. These include potent and uniquely sustained vasoconstriction of vascular smooth muscle, positive inotropy of myocardium, and the stimulation of cell proliferation or the hypertrophy in vascular smooth muscle cells, cardiac myocytes, and fibroblasts.

In vitro studies in cultured cells have established that ABT-627 selectively binds to the Eta receptor, and that ABT-627 is a potent inhibitor of ET-1 binding to the Eta receptor.

Studies in cultured human prostate cancer cells and other cultured cells have shown that ABT-627 acts as a functional antagonist of ET-1, and these effects have been confirmed in vivo by assessing the effect of ABT-627 on the ET-1 induced pressor response in rats. Further animal studies have suggested that oral ABT-627 may be effective in the treatment of congestive heart failure, pulmonary hypertension, hypertension, arterial restenosis, and myocardial infarction.

in addition to literature and animal models supporting the role of endothelin antagonists in cardiovascular indications, data exists supporting the role of the ET-1 cytokine as a pathogenic mediator in cancer.

The current role of endothelin in the manifestations of metastatic prostate cancer (PCA) and other tumors have yet to be fully defined. However, Abbott scientists and thought leaders have made multiple observations about endothelin biology which suggest that endothelin may play a role in the biology and pathophysiology of metastatic prostate disease and other metastatic disease such as ovarian, cervical and renal tumors

ABT-627 has successfully completed Phase II trials for PCA, and the results demonstrate efficacy in hormone refractory PCA. The end of Phase II meeting with the FDA was held on October 4th. The data from Phase II was very favorably received and "best package" comments were made. Fast track designation and rolling NDA were granted. The FDA was conceptually in agreement with preliminary design of Phase III clinicals and clinical end points to measure. While not a dictate, a second Phase III trial will likely be conducted to insure the best opportunity for a successful outcome. The Phase III program is scheduled to commence before year-end. It is expected that filing on ABT 627 will occur in US and ex-US 1Q 2004. The compound is also in Phase I trials for other cancer types. Phase II studies in other cancer types will commence in 2001. Other indications outside of oncology are also being considered, to optimize the commercial potential of this asset.

CONFIDENTIAL JH 008160

#### The US Market

Prostate cancer is the most common cancer to strike nonsmoking men. The NCI estimates that there are over 1.7 million men living with prostate cancer in the U.S., and another 179,300 will be diagnosed in 1999. Nearly 80% of these cases are men over 60 years of age. It is estimated that the prevalence of prostate cancer is 380,000 in Western Europe and 45,000 in Japan. While the vast majority of these patients will be identified with potentially curable disease (25% in Stage I and 50% in Stage II) in the U.S., half of these patients will go undiagnosed until late stage disease in W. Europe and Japan. The skewed distribution of diagnosed cases ex-U.S. is largely due to less aggressive prostate cancer screening programs compared to the U.S.

€

Prostate cancer has seen few additions or innovations in treatment regimens in the past two decades. Treatments remain, in general, radical prostatectomy (RP) for localized disease, radiotherapy for locally advanced disease and hormone therapy for advanced disease. Patients receiving hormone therapy become refractory to this treatment after two to three years, although many will continue on hormone therapy. These hormone refractory prostate cancer (HRPCa) patients usually have a life expectancy of approximately 12 months, and no existing standard of care exists for treating these patients. No therapy has shown a significant impact on survival in these patients, although some chemotherapeutic regimens may offer promise.

There is a general trend toward using hormone therapy in earlier stage patients. In some centers, patients are receiving hormone therapy prior to surgery or radiation, in an attempt to improve outcomes in these definitive treatments. Some thought leaders suggest that this earlier utilization has contributed to the overall mortality improvements in PCA. Studies are ongoing looking at different uses for hormone therapy, including intermittent therapy, in an attempt to improve outcomes and mitigate the morbidity associated with hormonal therapy.

Hormone therapy remains the mainstay of prostate cancer treatment in earlier stages. Chemotherapy, however, has gained additional attention in hormone refractory disease as new combinations and regimens offer the potential for greater therapeutic benefit with fewer side-effects. This trend will take several years before clinical trials are completed and community based oncologists adopt these regimens, so the current cytotoxic market in PCA is small.

The total dollar growth of this market has slowed as the two market leaders, Lupron (leuprolide/TAP) and Zoladex (goserelin/Zeneca), have experienced increased price pressures from managed care and Medicare. About half the states are currently reimbursing these therapies at a least cost option (only paying for the cheapest alternative), putting downward price pressures on Lupron (\$6,500/yr) to match Zoladex's (\$4,500/yr) lower price point. Thus, US Lupron dollar sales declined between 1997 and 1998, despite an increase in patient volume.

Growth has also stagnated due to a lack of innovation in this hormone dominated category. There have been few therapeutic advances in the treatment of PCA in the last 5 years.

The only chemotherapy approved for use in HRPCa patients with pain is Novantrone (mitoxantrone/Immunex), but the marginal benefits this compound delivers is deeply undercut by its severe toxicities and a lifetime cap on dose. Novantrone and steroids significantly reduced the metastatic pain in 40% of patients, but it does not appear to provide a survival advantage. Novantrone is dosed by i.v. infusion every 21 days, at a cost of \$560 per treatment, or an annual cost of around \$8,000. Use of this agent is associated with significant side-effects, including myelosuppression, cardiac toxicity (which limits dosing) and nausea. It is this negative side-effect profile that inhibits the use of this agent in more patients. Only about 4% of U.S. HRPCa patients received Novantrone therapy in 1998. Novantrone has not been approved ex-US.

Only about 17% of HRPCa patients received any chemothérapy in 1998. The most common drugs included estramustine, paclitaxel and etoposide. These drugs continue to be some of the most studied compounds in HRPCa ongoing research and represent the greatest short-term promise in the cytotoxic treatment of this advanced disease state.

€

<b>Q Q Q Q Q Q Q Q Q Q</b>			
Product	1997 Dollar Sales (MM)	1998 Dollar Sales (MM)	% chng '97-'98
Lupron (leuprolide/TAP)	\$650	\$667	2.6% 27.3
Zalodov (goserelin/Zeneca)	233 58	296 68	17.24
Casodex (bicalutamide/Zeneca) Eulixen (flutamide/Schering)	74 33	67 35	-9.5 6.1
Novantrone (mitoxantrone/Immunex) Nilandrone (nilutamide/Hoechst)	12	24	100 75
Emcyt (estramustine/Pharmacia/Upjohn)	8	8	100
Taxol (paclitaxel/BMS) VePesid (etoposide/BMS)	5	4	-20 14.8
Others	1,104	1,214	10%
Total			

Source: Tandem Research and Price Probe

 Novantrone (mitoxantrone/Immunex) is currently the only product approved for the treatment of hormone refractory PCA with pain. It currently falls short on the market needs in terms of of hormone refractory PCA with pain.
efficacy and side-effect profile.

Novantrone Profile
I I V intusion cycles
Expensive, ~\$10,000/yr
Provides marginal improvements in quality
of life
Yes
Dose limiting toxicities
108 oncology reps
Oncologists

Several surveys indicate that there are over 100 compounds in preclinical and clinical development for prostate cancer and various solid tumors. The compounds listed in the appendix represent compounds that appear to offer the greatest promise and/or potential for competition for ABT-627. However, since the most likely use of ABT-627 will be in combination with best therapy, it is difficult to define the extent of competitive threat that any of these compounds represent. In general, other cytostatic agents probably offer the greatest threat as a replacement for ABT-627. However, even other cytostatic agents may be combined to maximize the activity of the various mechanisms.

To date, PPD is aware of only one other endothelin receptor antagonist in development for cancer, from Yamanouchi, which began Phase I studies in the Fall of 1999. ABT-627 is still poised to be the first endothelin receptor antagonist to reach the market for oncology.

(

į

#### Scientific Rationale for ABT-627

There are relatively low hurdles for entry for a product to treat hormone refractory prostate cancer, as no truly effective agents presently exists. Quality of life is paramount in this population, followed by improvements in disease progression and survival. Quality of life parameters could include an impact on pain/or delay in pain onset or other performance type measures of daily activities. As all hormone therapy ultimately fails, a product that delays disease progression is needed.

Document 321-5

Improvements in QOL  Improvements in survival	Pipeline Impact     ABT-627's profile goal is to provide improvements to a patient's QOL or blunt a decrease in QOL     Cytotoxic agents rarely have significant positive impacts on QOL     Other cytostatic agents may offer this benefit     It is unlikely that improvements in survival will be seen in our current trials     Cytotoxic agents may offer a survival advantage, perhaps in combination with ABT-
	advantage, pernaps in combination was 5 627  • Cytostatic and cytotoxic agents offer the
Improvements in time to disease progression	greatest promise for this benefit

Our objective is to provide physicians and patients with a novel option for the treatment of hormone refractory prostate cancer, distinguish ABT-627 from current cytotoxic therapies and encourage the treatment of advanced prostate cancer patients currently only receiving hormonal therapy.

ABT-627 will be positioned as a physician and patient-friendly choice for advanced prostate cancer patients who have failed hormone therapy. ABT-627's novel mechanism of action provides a delay in disease progression and a positive impact on QOL. The oral, QD dosing enhances compliance and minimizes disruptions to daily living.

The message will focus on 3 key attributes:

- Efficacy (defined as increased time to tumor progression) in a patient group with few options
- Improvements in quality of life
- Convenience

Physicians no longer have to choose between treating advanced prostate cancer patients and a patient's quality of life. ABT-627 has a positive impact on disease progression and symptoms associated with quality of life, without the baggage of significant side-effects or the inconvenience of parenteral administration associated with current therapy choices.

This message expresses the key features of the agent in terms of patient benefits, as opposed to emphasizing the scientific/clinical aspects. Since prostate cancer is a terminal disease with a relatively long time for disease progression, the quality of a patient's life becomes even more critical. Especially in cancer treatment, where the therapy can often feel worse than the disease, the benefits that ABT-627 will bring, coupled with its benign side-effect profile, will have a significant impact on prostate cancer patients' lives.

#### Clinical Studies

Phase II trials have been completed and the data are being analyzed. Preliminary results for the primary endpoint of time-to-disease progression and the secondary endpoint of time-to-PSA progression show that ABT-627 favorably delays both phenomena with a benign adverse event profile. The results are summarized below:

Disease Progression: The delay in median time-to-disease progression for evaluable subjects was improved by 52% and 43% for the 10mg and 2.5mg doses respectively over the placebo time-todisease progression of 4.3 months.

Time-to-PSA Increase: A 150% and 150% improvement in median time-to-PSA progression for evaluable subjects was observed for the 10mg and 2.5mg doses respectively over the time-to-PSA progression placebo of 2 months.

Significant dose related decreases were observed in markers of metastatic bone disease.

#### **Key Prostate Cancer Competitors**

Product	Company	Phase	Projected NDA Filing		Anticipated impact on ABT-627
AG 3340	Agouron	111	2000	MMPI	In combination with mitoxantrone/prednisone. Unknown impact.
		. T	No. 25 %		
Marimastat	British Biotech	(1)-	2001	MMPI	Side-effect profile significantly worse than ABT-627. Probably minima impact.
SU 101	Sugen	1/11	2002	PDGF TK antagonist	Phase III in combination with mitoxantrone set to start in 1999. Uncertain impact.
AR 623	Aronex	ti	2002	All- transretinoic acid	IV liposomal form of ATRA. HRPCa trial began November 1998. Probably additive.
MGI 114	MGI Pharma	11	2002	Alkylating agent	Lead compound in acylfulvenes. Fairly toxic. Probably additive.
Liposomal Encapsulated . doxorubicin	NeoPharm and P&U/Alza and others	11	2002	Anthracycline	Various forms being developed by various companies. Probably additive.
Sataraplatin	BMS	111	2000	Platinum complex	Oral platinum analog w/toxicities comparable to carboplatin. Probably additive.
Taxol	BMS	II	2001	taxane	In various combinations with other chemo agents.  Probably additive.
Taxolere	RPR	11	2001	taxane	In various combinations with other chemo agents.  Probably additive.

CONFIDENTIAL

**ABT-594** 

## Descriptive Memorandum

P. E. Carrier and Committee of the State of the Committee of the Committee

**)** [

February 2001

**Abbott Laboratories** 

#### ABT-594 Opportunity Overview

1

ABT-594 is a non-opioid, non-NSAID analgesic that is a potent and selective neuronal nicotinic receptor (NNR) agonist being studied for the treatment of pain. ABT-594 is 30 to 100-fold more potent and equally efficacious to morphine in several well-characterized animal models of pain. The preclinical side effect and dependency liability profile of ABT-594 is superior to that of morphine.

ABT-594 is orally administered, and BID dosing is expected. Its initial targeted indication is symptomatic treatment of diabetic neuropathic pain. It is covered by a composition of matter patent through June of 2016, and also has a use patent pending in analgesia that would provide protection through September of 2017.

The IND filing of ABT-594 was in December 1998. A Phase IIb (dose ranging) trial began April 2000 in diabetic neuropathic pain. A Go/No Go decision for clinical efficacy is expected June 2001. The NDA filing is expected in 3Q2003. Development of additional formulations is under consideration (parenteral, transdermal, extended-release).

U.S. sales in 1999 for the key neuropathic pain treatments, Neurontin, carbamazepine, and tricyclic antidepressants (TCAs), are estimated to be \$350 million. Neurontin sales account for the bulk of this, with an estimated 40% of this antiepileptic drug's sales being for neuropathic pain. Neurontin's 2000 sales are expected to reach \$1 billion with perhaps 50% of its use in neuropathic pain. This dollar market value likely underestimates this market's potential due to a number of factors. Only the anticonvulsant, Tegretol (carbamazepine), currently off patent, and Lidoderm, a lidocaine patch, have specific indications for a type of neuropathic pain (trigernial neuralgia and post-herpetic neuralgia, respectively) in the U.S. Currently, there is an unmet market need for novel neuropathic pain treatments such as ABT-594. Therefore, this compound, is likely to be well received in this arena. Outside the U.S., Neurontin recently received an indication in the U.K for the treatment of neuropathic pain. Despite these opportunities, there has been little to no funding from the pharmaceutical industry to improve diagnosis and treatment of neuropathic pain and drive market growth.

Ex-U.S. sales of carbamazepine and Neurontin for treatment of neuropathic pain are estimated to be approximately \$140MM in 1999. Carbamazepine is still the treatment of choice ex-U.S., with estimated sales of approximately \$90MM in neuropathic pain. Neurontin has achieved only \$53MM in sales for this pain segment, with a price approximately 3-4 times that of carbamazepine, suggesting a patient share of only 10-20%.

Nociceptive pain is categorized by duration (acute or chronic) and by severity (mild, moderate, and severe). The mild and, to a lesser extent, moderate segments have multiple product entries and are generally well satisfied by OTC products such as aspirin, acetaminophen and ibuprofen. The prescription market for nociceptive pain is made up of four key classes of analgesics: NSAIDs, COX-2s, Opioids (and combination products), and Other Non-Opioids. In 1999, sales for these four classes of analgesics exceeded \$12BB (\$6.7BB U.S., \$5.6BB Ex-U.S.)

CONFIDENTIAL JH 008166

Page 2

#### Market Size / Prevalence

Pain is the most common symptom of disease and the most frequent complaint with which patients present to physicians. Chronic pain, including both neuropathic and nociceptive pain, is considered to be the single most common cause of suffering and disability in the industrialized world with an estimated 25-30% of the population experiencing some form of chronic pain.

Neuropathic pain is a frequent sequela of diabetes, cancer, AIDS and other viral infections, as well as entrapment neuropathies such as carpal tunnel syndrome. Diabetes and its associated complications are increasing at an alarming rate in the United States. Despite advances in treatment, the development of diabetic complications such as neuropathy remains significant. The diagnosed prevalence of diabetic neuropathy is estimated to be about 2 to 3 million patients, with at least 10 to 20% of those patients experiencing painful symptoms (~200,000 to 600,000.) AIDS-related neuropathic pain is estimated to affect approximately 40% of HIV-infected individuals (~14 million.) Post-herpetic neuralgia (PHN) is another virally induced neuropathic pain syndrome. Annually, acute herpes zoster infection (shingles) occurs in almost a quarter of a million people over the age of 60 in the U.S. alone. Pain lasting more than one year has been reported in 22% of patients over the age of 55 and in 48% of those over 70 years of age. In cancer, nerves can be damaged by mechanical distortion from a turnor mass, infiltration by tumor, chemotherapy, or radiation therapy and, therefore, neuropathic pain is common. An estimate of the prevalence rate for cancer-related neuropathic pain in the U.S. is 200,000 people.

Chronic nociceptive pain categories include osteoarthrifis (OA), chronic back and neck pain, rheumatoid arthritis (RA), and cancer pain. These diagnoses are expected to become more prevalent as the population ages. Current overall prevalence for these disorders is staggering (over 200 million worldwide) and, although the diagnosed and treated populations are lower, improved treatment options and awareness have the potential to drive significant growth. OA is one of the most common nociceptive pain conditions treated by primary care physicians and three-fourths of OA sufferers surveyed indicate that the disease interferes with their daily activities. Chronic back and neck pain are also highly prevalent and represent an estimated 40% of a primary care physician's (PCP's) chronic pain patient population.

CONFIDENTIAL JH 008167

ABT-594 201.doc CONFIDENTIAL Page 3

### Competition, Current Marketed Products:

C i

) {

The following tables show the factored U.S. and ex-U.S. prescription and sales volume for key neuropathic pain therapies in 1999.

	1999 Key Neurop	athic Pain Products	, Estimated TRxs	
Product/Class	1999 U.S. TRX (MM)	U.S. TRx CAGR '97-'99	1999 ex-U.S. TRx (MM)	ex-U.S. TRx CAGR '97-'99
Management	3.3	26.3%	N/A	N/A
Neurontin	1.0	12.6%	N/A	N/A
carbamazepine	8.2	1.1%	N/A	N/A
TCAs			N/A	N/A
TOTAL	12.5	5.6%	IN/A	

Source: IMS, factored for neuropathic uses.

N/A = not available

1	999 Key Neuropat	hic Pain Products,	Estimated \$ Sales	· · · · · · · · · · · · · · · · · · ·
Product/Class	1999 U.S. Sales	U.S. Sales ≕ CAGR '97-'99	1999 ex-U.S. Sales (\$MM)	ex-U.S. Sales CAGR '97-'99
Neurontin _	\$308	28.7%	\$53	57.6%
carbamazepine	\$17	13.1%	\$87	2.5%
	\$26	-3.3%	N/A	N/A
TCAS	\$351	21.7%	\$140	10.1%
TOTAL	\$301			and data from all

Source: IMS, factored for neuropathic uses; Ex-U.S. data includes retail pharmacy data from all audited markets

N/A = not available

#### Competition, Products in Development

Almost 100 compounds are currently in development for prescription pain management, though some of these compounds are also being developed for non-analgesic indications. Most of the analgesic compounds in the pipeline represent incremental improvements over the opioids or NSAIDs, or consist of new formulations or delivery mechanisms for the standard analgesics. Fewer than 30% of the compounds in development have novel mechanisms of action. Drugs with novel mechanisms are expected to provide the bulk of promoted competition for ABT-594.

In addition to the novel analgesics in the table below, a number of new formulation and combination products, most often containing an opioid, are in development. Second generation COX-2s are also in development but are not likely to represent major breakthroughs on the scale of the first generation products.

CONFIDENTIAL
JH 008168

ABT-594 201.doc CONFIDENTIAL Page 4

ž

i i		Ąnalgesia	Development Pipeline	– Key N	ovel Agents
1	Product	Company	Mechanism	Phase	Comments
· i	pregabalin	Pfizer	Unknown; possibly through (2 <sup>TM</sup> subunit binding	111	Neuropathic pain; chronic pain, follow-up to Neurontin
÷	saredutant	Sanofi	NK-2 receptor antagonist	II	General pain; MOA losing favor; active program
•	ZD4952, ZD 6416	Zeneca	Prostaglandin receptor antagonist	11	Moderate to severe pain, neurogenic pain
	GV196771	Glaxo	Glycine antagonist	11	Chronic pain; showing promise
1 {	Tepoxalin	Johnson & Johnson	COX/5-LO inhibitor	II	OA, described as 'steroid replacing anti-inflammatory drug'
	darbufelone	Parke-Davis	COX/5-LO inhibitor	11	General pain
	117mSn DTPA	Brookhaven National Lab/Diatide	Unknown		Cancer pain Bone cancer (preclinical)
1 L	cizôlirtinë : 1	Esteve :	Substance P agonist	11 .	Analgesia, antipyretic
	ADD . 234037/-	Houston University	Glycine NMDA associated antagonist	11 .	Neurogenic pain
	LY303870/	Eli Lilly	Neurokinin 1 antagonist	ll .	Pain (migraine – discontinued)
,	colykade devacade	Merck	Cholecystokinin B antagonists	11	Pain (UK)
	RPR 100893 dapitant	Aventis	Neurokinin 1 antagonist		Pain (France)
) :	prosaptide TX14A	Myelos Neurosciences	Unknown	1/11	Diabetic neuropathies, Pain
•	CNS 5161	Cambridge NeuroScience	Glutamate antagonist, NMDA receptor antagonist	I	Neurogenic pain
<b>b</b> 1	HCT-3012	NicOx	Nitric oxide NSAID	1	Pain and inflammation
7 1		IS, IMS, Decision	Resources, company re	ports	

CONFIDENTIAL JH 008169

Page 5 CONFIDENTIAL ABT-594 201.doc

Analgesia Devel	opment Pipel	ine – Nicotinic Mechanisms
Company	Phase	Comments
Taisho	(1	Target is Alzheimer's disease; may have preclinical pain program; looking for partner
Cytomed	Preclinical	Target is pain; epibatidine analog
Sibia	Preclinical	Target is pain
Fidia	Preclinical	Target is pain; not actively funding
	Company Taisho Cytomed Sibia	Taisho II  Cytomed Preclinical Sibia Preclinical

#### Unmet Needs

In general, a significant unmet need exists for safer, non-abusable, non-addicting, non-tolerance-producing, and non-scheduled efficacious oral and parenteral analgesic products for the treatment of moderate to severe neuropathic and chronic nociceptive pain.

Unmet Market Needs and the Impact of the Pipeline			
Unmet Need	Pipeline Impact		
Efficacy in moderate to severe pain without tolerance, dependence or abuse potential	Novel nicotinic agents like ABT-594 may provide efficacy in more severe pain states without opioid-like liabilities.		
Efficacy in neuropathic pain	Pregabalin may provide incremental improvement in neuropathic pain efficacy over gabapentin, but may also have increased frequency of adverse events.		
٠	Novel nicotinic agents like ABT-594 appear to have efficacy in neuropathic pain, based on animal models.		
Reduction in the GI bleeding risk of NSAIDs	COX-2 inhibitors appear to reduce the incidence and severity of 0 ulcers and bleeding; second generation COX-2s may increase therapeutic window further; ABT-594 may need to demonstrate to G.I. complication rate.		
Overcome ceiling effect of NSAIDs	Preclinical studies did not indicate a ceiling effect for novel nicoti agents like ABT-594.		
Extended dosage intervals or novel delivery mechanisms for improved compliance and convenience	Once weekly dosing formulations being explored for COX-2s, etc Transdermal patch technology improvements likely; may need to provide line-extension / alternate formulations for ABT-594.		
Therapies aimed at disease modification, prevention	Agents that decrease rate of diabetic complications (e.g., aldose reductase inhibitors) or directly treat neuropathy (bimoclomol) madecrease incidence of neuropathic pain; thereby decreasing available market for ABT-594.		

CONFIDENTIAL JH 008170

ART-594 201 doc CONFIDENTIAL Page 6

#### Product / Development Background

#### Scientific Rationale for ABT-594

Recent findings in the understanding of pain mechanisms have led to new conceptual approaches to clinical pain and a new understanding of potential novel molecular targets for analgesic drug development. Molecular targets have included modulators of glutamate neurotransmission (NMDA antagonists), ion channel modulators (neuron specific calcium channels, TTX-resistant sodium channels), neurokinin antagonists (NK-1), and novel anti-epileptics targeting the calcium receptor. None of these approaches has yet produced compounds exhibiting broad-spectrum analgesic efficacy with decreased side effect liability.

ABT-594 is a non-opioid, non-NSAID analgesic that is 30- to 100-fold more potent and equally efficacious to morphine in treating moderate to severe pain in several well-characterized animal models of pain. The preclinical side effect and dependence liability profile of ABT-594 is superior to that of morphine. Mechanistically, ABT-594 is a potent and selective neuronal nicotinic receptor (NNR) agonist with high oral bioavailability in rat, dog, and monkey.

In pre-clinical studies, ABT-594 rapidly distributes to the brain following systemic administration and, like morphine, can work at multiple levels in the central and peripheral nervous system to modulate pain perception. ABT-594 produces antinociceptive effects by interacting at both central and peripheral nAChRs. Injections of ABT-594 into brain at doses 1000-fold lower than given peripherally produce marked antinociceptive activity, indicating that ABT-594 can also activate descending pathways from the CNS to modulate pain processing. It also inhibits the release of the primary nociceptive transmitters, substance P and calcitonin gene related peptide (CGRP) in vitro, at the level of the dorsal horn of the spinal cord suggesting that ABT-594 can attenuate mechanisms leading to neurogenic inflammation, central sensitization and consolidation of pain-mediated neuronal changes.

ABT-594 is expected to be a highly differentiated product. It is expected to be the first neuronal nicotinic receptor agonist to receive an indication for pain. It has a novel mechanism of action and a potentially broad coverage of chronic pain conditions. In addition, it has an opioid-like efficacy without tolerance, dependence or abuse potential, while having equivalent/superior efficacy to other drugs used to treat neuropathic pain.

#### Clinical Studies

1

Human clinical trials began in 1997. Phase I trials with an oral solution formulation indicated that 150ug/day would be the maximum tolerated dose. Results from subsequent phase I and phase II trials with soft elastic capsule (SEC) and hard gelatin capsule (HGC) suggest that higher doses would be tolerated. Phase IIa studies with ABT-594 SEC formulation suggest a trend towards analgesic effect at 75ug BID, the maximum dose studied in this protocol. ABT-594 was generally well tolerated in these studies. The most common adverse events for subjects receiving ABT-594 75ug BID were nausea (15%), headache (13%), dizziness (7%), insomnia (6%), and vomiting (5%).

A phase IIb study for neuropathic pain at higher, titrated doses of ABT-594 began in April 2000 and ends in June 2001. A total of 320 patients is anticipated to be included in the study.

CONFIDENTIAL
JH 008171

ABT-594 201.doc CONFIDENTIAL Page 7

#### Considerations

#### Target Profile:

The current status of ABT-594's profile vs. target profile is summarized in the table below:

Target Profile Attribute	Probability
Not scheduled (DEA)	High
Very few abnormal Liver Function Tests	High
Few Drug interactions	High
BID / TID dosing	High
No reduced efficacy or increased AEs in nicotine users	High
Onset of action 1.5 – 2.0 hours	High
Neuropathic efficacy	Medium
No tolerance, dependence or withdrawal	Medium
Other safety OK	Medium
No cravings in ex-nicotine users	Medium
ر مربع به Low nausea / vomiting	Low

#### Label Strategy.

BASE: Indicated for the treatment of diabetic neuropathic pain.

**UPSIDE:** 

- 1) Treatment of pain associated with OA
- 2) Treatment of post-herpetic neuralgia
- 3) Treatment of neuropathic pain
- 4) Treatment of chronic pain
- 5) Treatment of cancer pain

#### Cost of Goods Sold:

The projected average daily dose is expected to be a maximum of approximately 600 mcg base equivalent / day. Based upon this dosage projection and the estimated cost of bulk drug substance of \$40M per Kg base equivalent, the estimated cost for drug substance at launch will be approximately \$0.024 per day.

CONFIDENTIAL JH 008172

ABT-594 201.doc CONFIDENTIAL Page 8

#### Pricing:

US: Pricing new, and particularly novel, products at a reasonable premium will likely continue to be the norm in the years leading up to the launch of ABT-594. Current forecast assumptions put the price of ABT-594 at a level comparable to Celebrex and Neurontin, grown at a modest 2% per year to launch year AWP of approximately \$95 for a 30 day prescription.

Ex-US: New pain medications must demonstrate a true advantage in efficacy and/or side effects to receive regulatory approval, especially by the European Medicines Evaluation Agency (EMEA); assuming the target efficacy and tolerability profile of ABT-594 is achieved, ABT-594 would meet this requirement. Because ABT-594 may have application in both neuropathic and chronic nociceptive pain, the ex-U.S. pricing assumption for ABT-594 is comparable to COX-2 pricing. The current average price for COX-2's is approximately \$1.10 per day; however, this reflects a large percentage of sales in "free-pricing" countries, where COX-2s launched first, which tend to have higher than average prices. Therefore, the average ex-U.S. price for ABT-594 is assumed to be \$0.90/day.

> CONFIDENTIAL JH 008173

Page 9 CONFIDENTIAL ABT-594 201.doc

CONFIDENTIAL

**ABT - 751** 

# **Descriptive Memorandum**

February 2001

Abbott Laboratories

#### ABT-751

C

) €.

#### Opportunity Overview

Cytotoxic agents and hormones constitute the dominant classes of drugs available to treat cancer and are responsible for 96% of the total market. Since 1993, Taxol, a taxane developed and marketed by BMS, has been widely used. Another taxane, Taxotere, developed and marketed by Aventis, was launched in 1996. Combined worldwide sales of these two products were of nearly \$2 Billion US in 1999. Clinically, the development of drug resistance is the primary factor that limits the efficacy achievable with these drugs.

Abbott's anti-mitotic agent (ABT-751) is a novel, oral cytotoxic agent that acts by a mechanism similar to that of the taxanes but retains activity against taxane resistant cells. ABT-751 binds to the colchicine site on tubulin and inhibits the *in vitro* polymerization of microtubules. The interference with normal microtubule dynamics leads to a block in the cell cycle at the G2/M phase that ultimately results in the induction of cellular apoptosis. ABT-751 is a potent antimitotic agent that inhibits the proliferation of a broad spectrum of human tumor derived cell lines including those that are paclitaxel and doxorubicin resistant due to the multidrug-resistant (MDR) phenotype or other genetic changes.

ABT-751 demonstrated impressive oral antitumor activity when evaluated in both synegeic and human xenograft tumor models. The antitumor response was independent of the MDR status of the model, consistent with the activity observed in cell cultures. In sharp contrast with other cytotoxic drugs, the maximum tolerated dosage of ABT-751, on a.g.d. 1-5 schedule, could be administered for an extended period (q.d. 1-21 or q.d. 1-28) resulting in a dramatic enhancement of the antitumor activity. These results suggest that the colchicine site ligands, such as ABT-751, will exhibit a broad spectrum of activity that will be distinct from that of other classes of antimitotic drugs. Oral availability of the compound is high. Taxol and Taxotere, in contrast, have no oral bioavailability.

The most significant finding in toxicology studies was a change in systemic and pulmonary vascular resistance following intravenous infusion of ABT-751 to anesthetized dogs. These effects led to an inverse response in cardiac output. Similar changes were observed following infusion of a structurally unrelated colchicine-site ligand, and therefore most likely represent a class effect. Additional toxicology studies focusing on vascular pathology will be performed to further elucidate this finding.

ABT-751 was administered to patients with advanced cancer in Japan in a Phase I study. Toxicities seen after single doses and 5 days of q.d. dosing were nausea, vomiting, diarrhea, epigastric pain, ileus and peripheral neuropathy. Grade 2 toxicity was peripheral neuropathy and associated paresthesias. Pharmacokinetic analyses showed plasma concentrations equivalent to those that affected systemic resistance and cardiac output in the anesthetized dog study. However, no adverse cardiovascular effects were observed in the Japanese Phase I trial. Evidence of ABT-751 efficacy was exhibited in one patient with uterine sarcoma, one patient with NSCLC after single doses, one patient with gastric cancer and one patient with uterine cervical carcinoma demonstrated decreased tumor markers after repeated dosing.

The planned initial Phase I study in the U.S. will determine the maximum tolerated dose and dose-limiting toxicities of ABT-751 given orally once a day or twice daily for multiple cycles in patients with advanced malignancies. In addition, pharmacokinetics in a western population, and optimal dose and schedule will be determined. Phase II studies will be initiated in patients with different cancer types:

- •Refractory breast (taxane failures).
- Hormone refractory prostate
- Bladder
- -Lung

CĪ

) **E** 

- Cervical
- ·Hepatocellular
- Other possibilities: colorectal, sarcoma, renal cell, pancreatic, HNSCC

Cytotoxic agents represent the largest, and fastest growing, class of oncology agents by sales volume. The following chart summarizes the value of the current oncology market

#### Global Sales by Market Segment (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
Hormone	4,414	4,784	4,884	5,000	5.2%
Cytotoxic	4,278	5,212	6,268	7,300	21.0%
Adjunctive	3,367	3,651	4,166	4,900	11.2%
Total	12,059	13,647	15,318	17,200	12.7%

Source: Datamonitor

#### Sales by Region (\$ MM)

	*	• • • •			
	4000 Calaa	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
	1996 Sales			8.500	15.5%
-110	5,564	6,276	7,422	6,500	10.070
US	3,304		= 000	8,700	10.3%
Fx-US	6,495	7.370	7,896	6,700	10.070
EX-US	0,730				

Source: Datamonitor

This growth of the cytotoxic segment has been driven primarily by the introduction of new, more effective and expensive therapies such as Taxol (paclitaxel/BMS), Gemzar (gemcitabine/Lilly), Taxotere (docetaxel/RPR) and Hycamtin (topotecan/SB). Uptake of these newer agents, however, can be dependent on the cost sensitivity of the local market.

The clinical targets identified for this compound include late stage breast cancer, late stage NSCL cancer (on-label), with late stage ovarian and pancreatic cancer as additional cancer types where efficacy has been demonstrated, but not filed. This product may also be potentially efficacious in cancers such as gastric, colorectal, prostate, bladder, esophageal, hepatocellular (ex US), lymphoma, and leukemia. Targets will be refined as we know more about this compound's invivo activity.

The following tables summarize the key competitive products by indication (US data only):

Late Stage Breas	st
Product	Share
Cyclophosphamide/Cytoxan/BMS	18.7
Doxorubicin/Adriamycin/P&U	17.11
Docetaxel/Taxotere/RPR	16.25
Paclitaxel/Taxol/BMS	16.11
Trastuzumab/Herceptin/Genetech	11.26

Late Stage NSCL		
Product	Share	
Carboplatin/Paraplatin/BMS	50.32	
Paclitaxel/Taxol/BMS	44.14	
Vinorelbine/Navelbine/Glaxo	22.78	
Gemcitabine/Gemzar/Lilly	22.14	
Cisplatin/Platinol/BMS	11.28	

Late Stage Over	Share
Paclitaxel/Taxol/BMS	47.11
Carboplatin/Paraplatin/BMS	45.42
Topotecan/Hycamtin/SKB	22.54
Dox SL/Doxil/Alza	9.14
Cisplatin/Platinol/BMS	7.58

Late Stage Pancreas		
Product	Share	
Gemcitabine/Gemzar/Lilly	78.5	
5-FU/Efudex/ICN Pharma Leucovorin/	21.0	
	10.7	
Cisplatin/Platinol/BMS	4.72	

#### Compounds in Development

ţ

ABT-751 induces a mitotic block by binding to the colchicine site on tubulin and thereby affecting tubulin polymerization. There are no currently available drugs which function by the mechanism described above. However, vinca alkaloids and taxanes fall into the broad category of antimitotics although they produce the anti-mitotic effect through different mechanisms. The following table summarizes anti-mitotic compounds in development.

Servier   Vinxaltine   Cancer (unspecified)   Phase I   Unknow	Company	Compound		Status of compound	Status of project
Display					
Tularik T138607 (phosphate prodrug)  Tularik T900607 Cancer (unspecified) Preclinical active ICI/CRC Amphethinile Cancer (unspecified) Phase I (abandoned 1988) inactive Welcome 1069C Cancer (unspecified) Phase I (abandoned 1996) inactive Research Trimethylcolchicinic acid Various turnors Phase I (1990, abandoned) inactive Vinca alkaloid-site ligands  BASF LU103793 Cancer (unspecified) Phase II (abandoned 2000) inactive Vinca alkaloid-site ligands  BASF LU103793 Cancer (unspecified) Phase II (abandoned) active Vinca alkaloid-site ligands  Servier Vinxatine Cancer (unspecified) Phase I (abandoned) active Unknow NCI dolastatin 10 Adv. Cancers Phase I (abandoned) active Unknow (abastatin 10 Adv. Cancers Phase I (abandoned) active Unknow (abastatin 10 Adv. Cancer (unspecified) Phase I (abandoned) active Unknow (abastatin 10 Adv. Cancers Phase I (abandoned) active Unknow (abastatin 10 Adv. Cancers Phase I (abandoned) active Unknow (abastatin 10 Adv. Cancer (unspecified) Phase I (abandoned) active Unknow (abastatin 10 Adv. Cancers Phase I (abandoned) active Unknow (abastatin 10 Adv. Cancer (unspecified) Phase I (abandoned) active Unknow (abastatin 10 Adv. Cancer (unspecified) Preclinical unknow (abastatin 10 analog) Preclinical Unknow (abastatin 10 analo	Oxigene	combretastatin-A4	Tumor vasculature	Phase I	
Tularik T900607 Cancer (unspecified) Preclinical active ICI/CRC Amphethinile Cancer (unspecified) Phase I (abandoned 1988) inactive Welcome Research 1069C Cancer (unspecified) Phase I (abandoned 1996) inactive Research Trimethylcolchicinic acid Various tumors Phase I (1990, abandoned) inactive Various tumors CI-980 Ovarian, colorectal Phase II (abandoned 2000) inactive Vinca alkaloid-site ligands  BASF LU103793 Cancer (unspecified) Phase II (abandoned) active Vinxaltine Cancer (unspecified) Phase I (abandoned) active NCI dolastatin 10 Adv. Cancers Phase I unknow TzT-1027 (dolastatin 10 Cancer (unspecified) Phase I (Jpn) unknow (cryptophycin 52) Cancer (unspecified) Preclinical unknow (cryptophycin 52) Cancer (unspecified) Preclinical unknow Microtubule stabilizing agents (non-taxanes)  Soc. Biotech. Res/ Bristol-Myers Squibb Bristol-Myers Squibb Sarcodictyins Cancer (unspecified) Preclinical active Inspecified Sarcodictyins Cancer (unspecified) Preclinical active Active Inspecified Sarcodictyins Cancer (unspecified) Preclinical active Inspecified Sarcodictyins Preclinical Active Inspecified Sarcodicty Inspecified Sarcodicty Insp	Tularik	T138607 (phosphate	Cancer (unspecified)	Phase I	
Collaboration   Content			Cancer (unspecified)		
Welcome Research 1069C Cancer (unspecified) Phase I (abandoned 1996) inactive Research NIH Trimethylcolchicinic acid Various tumors Phase I (1990, abandoned) inactive Parke-Davis CI-980 ovarian, colorectal Phase II (abandoned 2000) inactive Vinca alkaloid-site ligands  BASF LU103793 Cancer (unspecified) Phase II (abandoned) active Vinxaltine Cancer (unspecified) Phase I unknow NCI dolastatin 10 Adv. Cancers Phase I unknow TZT-1027 Cancer (unspecified) Phase I (Jpn) unknow (dolastatin 10 analog)  Lilly LY 355703 Cancer (unspecified) Preclinical unknow Maitansine Cancer (unspecified) Preclinical unknow Microtubule stabilizing agents (non-taxanes)  Soc. Biotech. Epothilone Cancer (unspecified) Preclinical active Res/ Bristol-Myers Squibb  Bristol-Myers Squibb  Pharmacia & Sarcodictyins Cancer (unspecified) Preclinical active Active Inspecified) Preclinical active Active Inspecified Preclinical active Active Inspecified Preclinical active Active Inspecified Preclinical active Active Inspecified Preclinical Activ				Phase I (abandoned 1988)	
NIH Trimethylcolchicinic acid Various tumors Phase I (1930, abandoned 2000) inactive Parke-Davis CI-980 ovarian, colorectal Phase II (abandoned 2000) inactive Vinca alkaloid-site ligands  BASF LU103793 Cancer (unspecified) Phase II (abandoned) active (dolastatin 15 analog)  Servier Vinxaltine Cancer (unspecified) Phase I unknow NCI dolastatin 10 Adv. Cancers Phase I unknow TZT-1027 Cancer (unspecified) Phase I (Jpn) unknow (dolastatin 10 analog)  Lilly LY 355703 Cancer (unspecified) Preclinical unknow Maitansine Cancer (unspecified) Preclinical unknow Microtubule stabilizing agents (non-taxanes)  Soc. Biotech. Res/Bristol-Myers Squibb Eristól-Myers Squibb Cancer (unspecified) Preclinical active Active Pharmacia & Sarcodictyins Preclinical Active Active Pharmacia & Sarcodictyins Preclinical Active Preclinical Active Preclinical Active Pharmacia & Sarcodictyins Preclinical Active Preclinical Active Preclinical Active Pharmacia & Sarcodictyins Preclinical Active Preclinical Active Preclinical Active Preclinical Active Preclinical Active Pharmacia & Sarcodictyins Preclinical Active Preclinical Acti	Welcome			Phase I (abandoned 1996)	
Parke-Davis   CI-980   ovarian, colorectal   Phase II (abandoned 2000)   inactive		Trimethylaplahicinic acid	Various tumors		inactive
Vinca alkaloid-site ligands  BASF LU103793 Cancer (unspecified) Phase II (abandoned) active  Servier Vinxaltine Cancer (unspecified) Phase I unknow  NCI dolastatin 10 Adv. Cancers Phase I unknow  NCI Teikoku TZT-1027 Cancer (unspecified) Phase I (Jpn) unknow  Hormone (dolastatin 10 analog)  Lilly LY 355703 Cancer (unspecified) Preclinical unknow  Microtubule stabilizing agents (non-taxanes)  Soc. Biotech. Res/ Bristol-Myers Squibb  Bristol-Myers Squibb  Pharmacia & sarcodictyins  Cancer (unspecified) Preclinical active  Cancer (unspecified) Preclinical active  Preclinical active  Cancer (unspecified) Preclinical active  Cancer (unspecified) Preclinical active				Phase II (abandoned 2000)	inactive
BASF (dolastatin 15 analog)  Servier Vinxaltine Cancer (unspecified) Phase I (abandoned)  NCI dolastatin 10 Adv. Cancers Phase I (Jpn)  Teikoku TZT-1027 (dolastatin 10 analog)  Lilly LY 355703 (cryptophycin 52)  Takeda Maitansine Cancer (unspecified) Preclinical unknow Microtubule stabilizing agents (non-taxanes)  Soc. Biotech. Res/ Bristol-Myers Squibb  Bristol-Myers Squibb  Phase I (Jpn) unknow Phase I (Jpn)  Cancer (unspecified) Preclinical unknow Preclinical unknow Preclinical unknow Preclinical unknow Preclinical active Active Squibb  Cancer (unspecified) Preclinical active Preclinical active Preclinical active Squibb  Bristol-Myers Squibb Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active Active Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active Preclinical active Preclinical active Preclinical active Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active	Parke-Davis	Vines alkaloid-site li			
Servier Vinxaltine Cancer (unspecified) Phase I unknow dolastatin 10 Adv. Cancers Phase I unknow TZT-1027 (dolastatin 10 analog) Phase I (Jpn) Unknow Lilly LY 355703 (cryptophycin 52) Cancer (unspecified) Preclinical unknow Microtubule stabilizing agents (non-taxanes)  Soc. Biotech. Epothilone Cancer (unspecified) Preclinical active Res/ Bristol-Myers Squibb Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active Active Preclinical active Preclinical active Active Active Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active Act	BASF	LU103793	Cancer (unspecified)	Phase II (abandoned)	active
NCI dolastatin 10 Adv. Cancers Phase I unknow TZT-1027 Cancer (unspecified) Phase I (Jpn) Unknow (dolastatin 10 analog)  Lilly LY 355703 Cancer (unspecified) Preclinical Unknow (cryptophycin 52)  Takeda Maitansine Cancer (unspecified) Preclinical Unknow Microtubule stabilizing agents (non-taxanes)  Soc. Biotech. Epothilone Cancer (unspecified) Preclinical active Res/ Bristol-Myers Squibb  Bristol-Myers eleutherobin Cancer (unspecified) Preclinical active Squibb  Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active			Cancer (unspecified)	Phase I	unknown
Teikoku TZT-1027 Cancer (unspecified) Phase I (Jpn) unknow (dolastatin 10 analog)  Lilly LY 355703 Cancer (unspecified) Preclinical unknow (cryptophycin 52)  Takeda Maitansine Cancer (unspecified) Preclinical unknow Microtubule stabilizing agents (non-taxanes)  Soc. Biotech. Epothilone Cancer (unspecified) Preclinical active Res/ Bristol-Myers Squibb Bristól-Myers eleutherobin Cancer (unspecified) Preclinical active Squibb  Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active				Phase I	unknown
Lilly LY 355703 Cancer (unspecified) Preclinical Unknow (cryptophycin 52)  Takeda Maitansine Cancer (unspecified) Preclinical Unknow Microtubule stabilizing agents (non-taxanes)  Soc. Biotech. Epothilone Cancer (unspecified) Preclinical active Res/ Bristol-Myers Squibb  Bristol-Myers eleutherobin Cancer (unspecified) Preclinical active Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active	Teikoku	TZT-1027		Phase I (Jpn)	unknown
Takeda Maitansine Cancer (unspecified) Preclinical different Microtubule stabilizing agents (non-taxanes)  Soc. Biotech. Epothilone Cancer (unspecified) Preclinical active Res/ Bristol-Myers Squibb  Bristól-Myers eleutherobin Cancer (unspecified) Preclinical active Squibb  Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active		LY 355703	Cancer (unspecified)	Preclinical	unknown
Microtubule stabilizing agents (non-taxanes)  Soc. Biotech.	<u> </u>		Cancer (unspecified)	Preclinical	unknown
Soc. Biotech. Res/ Bristol-Myers Squibb Bristól-Myers eleutherobin Cancer (unspecified) Preclinical active Squibb Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active	Takeda				<u> </u>
Bristol-Myers Squibb Bristol-Myers eleutherobin Cancer (unspecified) Preclinical active Squibb Pharmacia & sarcodictyins Cancer (unspecified) Preclinical			Cancer (unspecified)	Preclinical	active
Bristol-Myers eleutherobin Cancer (unspecified) Preclinical active  Pharmacia & sarcodictyins Cancer (unspecified) Preclinical active	Bristol-Myers		•		
Pharmacia & sarcodictyins Cancer (unspecified) Preclinical	Bristol-Myers	eleutherobin	Cancer (unspecified)	Preclinical	active -
I I I DOOD	Pharmacia &	sarcodictyins	Cancer (unspecified)	Preclinical	
Takeda GS-164 Cancer (unspecified) Preclinical active	Upjohn	GS-164	Cancer (unspecified)	Preclinical	active

The novelty of this mechanism offers the promise of differentiation that will diminish the threat from potential competitors. However, this novelty is balanced by the similarity to current mechanisms, such as taxanes and vinca alkaloids, which suggests the promise of clinical efficacy. With the opportunity to be first or second to market with an agent that binds to the colchicine site, the competitive situation seems modest.

₽ €

CONFIDENTIAL

ABT - 492

# **Descriptive Memorandum**

February 2001

**Abbott Laboratories** 

JH 008179

**ABT 492** 

C į

∌ €

The commercial success of fluoroquinolones such as ciprofloxacin and levofloxacin, along with the desire to further improve the properties of these compounds (microbiological spectrum and safety, for example) has led to fierce competition to identify analogs with superior therapeutic properties. In addition, the development of resistance to present antibiotics will drive a continued need for new agents. Goals for a quinolone antibiotic include broad-spectrum indications equal to trovafloxacin, antibacterial activity comparable to trovafloxacin, tolerability comparable to levofloxacin, oral and intravenous formulations, once daily dosing, length of treatment equal to moxifloxacin, and an acceptable cost of goods. ABT-492, an in-licensed compound from the Wakunaga Pharmaceutical Co., is being developed for evaluation to meet these goals:

The in vitro antibacterial activity of ABT-492 was consistently more potent than trovafloxacin against most quinolone-susceptible pathogens, including species responsible for community and nosocomial respiratory tract infections, urinary tract infections, blood stream infections, skin and skin structure infections, and anaerobic infections. The compound has potent activity against multidrug-resistant S. pneumoniae (penicillin-, macrolide-, tetracycline-resistant) and retained activity against S. pneumoniae strains resistant to other quinolones including trovafloxacin. ABT-492 was also highly active against anaerobes and ciprofloxacin-susceptible P. aeruginosa. ABT-492 was as active as trovafloxacin against C. trachomatis, indicating good intracellular penetration. Thus, ABT-492 is likely to be a useful broad-spectrum antibacterial agent. The enhanced antibacterial activity of ABT-492 relative to ciprofloxacin, levofloxacin, and trovafloxacin is likely to be explained, in part, by it's potent interactions with bacterial topoisomerases. ABT-492's equivalent activity against both the DNA gyrase and the topoisomerase IV of pathogens, give ABT-492 a potential for decreased development of resistance.

The in vitro potency data suggests that ABT-492 has the potential to be therapeutically effective at doses comparable to trovafloxacin and superior to levofloxacin. In addition, ABT-492 was consistently more potent than trovafloxacin against MRSA and vancomycin-resistant enterococci. In both these cases, however, therapeutic utility remains to be assessed in the clinical setting.

S. pneumoniae was chosen as the dose-defining pathogen since it is the key pathogen in severe respiratory tract infections and treatment of infections caused by this pathogen has traditionally been a weakness of most quinolones. For treatment of fluoroquinolone-susceptible S. pneumoniae respiratory tract infections, oral dosing may be similar to trovafloxacin based on data generated in lung infection models. Because of the excellent potency of ABT-492 against fluoroquinolone-resistant S. pneumoniae with an MIC<sub>90</sub> of 0.12 μg/ml, this group of emerging strains may be targeted as a key differentiation point from other quinolones. Also, data from the thigh infection model suggests significantly greater efficacy for ABT-492 than for trovafloxacin.

#### The Market

ABT-492 is broad-spectrum anti-infective agent with potential application across a broad range of indications, including respiratory infections, genito-urinary infections, and skin/soft tissue infections. It is assumed that a pediatric formulation would not be a part of the primary development plan due to the known adverse events caused by quinolones in pediatric populations. Nonetheless, reports of quinolone pediatric development has been reported (gatifloxacin), hence the pediatric market should be regarded as a potential upside for this quinolone should its safety profile merit its use in pediatrics.

#### **Current Treatment Options**

ſ. í

) Í .

Juneau Troubles		Comments
Class	Mechanism of Action	Mostly generic, class has seen significant decrease
Penicillins	Cell wall synthesis inhibitor	as a result of penicillin resistance.  Some generic, class has seen significant decrease in
Cephalosporins	Cell wall synthesis inhibitor	use as a result of prevalence of B-lactamase producing strains and modification of penicillin-binding
Tetracyclines	Protein synthesis inhibitor	Generic agents, relatively high levels of resistance but are still useful in some indications
Sulfonamides	Folic acid synthesis	Generic agents, relatively high levels of resistance but are still useful in some indications  Widespread use in RTI, macrolide resistance has
Macrolides	Protein synthesis inhibitor	been increasing rapidly, but has not yet translated into declines in clinical efficacy; H. flu activity continues to be class weakness, along with GI adverse events, days interactions. & taste perversion
Quinolones	DNA synthesis inhibitor	Fastest growing antibiotic class, used in a broad spectrum of indications; class historically associated with poor Gram+ pathogen coverage and sub-optimal safety profiles; newer agents (Levaquin, Tequin, Avelox) have improved dramatically along both spectrum and safety dimensions.
Oxazolidinones	Protein synthesis inhibitor	Newest antibiotic class to reach market, due to limited Gram- profile will be used primarily in nosocomial setting

#### U.S. Market

1999 U.S. antibiotic prescription and sales data are presented in the table below.

			700 É	1996	1997	1998	1999	CAGR95-99
			1995			208	221	0.1%
	s)	Tab/Cap	220	215	211 63	59	61	-5.3%
[ [	TRXs (MM)	Oral Susp.	76	66	NA	NA	NA	NA
S	)	I.Y	NA	NA_		\$4,848	\$5,715	8.9%
D	% <del>≥</del>	Tab/Cap	\$4,057	\$4,220	\$4,467	\$1,001	\$1,120	1.0%
	Sales (\$MM)	Oral Susp.	\$1,075	\$979	\$977	\$1.890	\$2.117	3.2%
	- 5	I.V.	\$1.865	\$1.829	\$1.855	31.070	<u> </u>	

Tab/cap and oral suspension prescriptions had been declining 1-2% per year in the period of 1995-1998, presumably from increased attention to appropriate prescribing in the face of increasing resistance, however, prescriptions recovered in 1999, though this may be explained at least in part by a relatively late 1998-99 flu season. Even in the face of this negative pressure on antibiotic use, however, sales in the U.S. have continued to increase, particularly in the tab/cap market. This is due to the trend of replacing relatively low-cost generic agents with higher priced premium antibiotics; during 1995-1999, generic tab/cap prescriptions declined by 30MM. So while negative pressure on the use of these antibiotics continues, it appears the market is willing to bear higher costs for agents that meet unmet need. The IV market has grown slightly in terms of sales, also being driven largely by the replacement of generic agents with more costly branded agents.

Avelox.

(

1

Ex-U.S. sales of antibiotics totaled \$11.7 billion in 1999. The tab/cap represents the largest Ex-U.S. Market segment, with sales of \$9.4 billion on 770 MM TRX. TRX growth has been flat, with a 1996-99 CAGR of 0.5%; the use of antibiotics is predicted to slowly decline due to more judicious use of antibacterials in the face of increasing bacterial resistance.

Ex-US, the quinolone class accounted for 8% (62MM) of total tab/cap market prescriptions and 13% of sales (\$1.2 billion). Ciprofloxacin is the market leader ex-US, with approximately 47% of the quinolone market Rxs (29MM) and 44% (\$530MM) of sales. Levofloxacin launched in many European markets in 1998/1999 and holds approximately 14% Rx share of the European quinolone market, and 0.8% of the overall tab/cap market. Although grepafloxacin and trovafloxacin also launched in some European countries in 1999, both products were recently pulled from the market due to liver toxicity and other complications. Moxifloxacin launched in Germany in Q4 1999, but has not yet been approved in other markets. In Japan, levofloxacin launched in 1994 and still commands a 65% Rx share of the quinolone market and 10% of the Japanese tab/cap market overall. Japan accounts for approximately 80% of ex-US levofloxacin sales (\$370MM).

	1999 Ex-US Tab/	Cap Market				Γ
Class	Sales (SMM)	Sales Share	Sales CAGR 96-99	TRXs (MM)	TRX Sháre	TRX CAGR '96-'99
	\$9,348	1-	3.6%	770		0.8%
Market  Quinolone Class	\$1219	13%	-12%	62	8%	NA_
Cipro	\$530	5.7%	4.9%	29	3.8%	NA_
Levaquin	\$466	5.0%	NA	18	2.3%	NA_
Trovan	\$12	0.1%	NA	0.5	0.1%	NA

#### Competition

The anti-infective pipeline is very competitive, but most of the competition is focused on improving the activity and safety of the quinolones. Ketolide development is the only other area of activity which is in late stage of development. The quinolone compounds in present development may fall out because of safety or lack of activity against resistant pathogens.

		Co	mpetitive Analysis	– Emergii	ng Competition
Product	Company		Phase/Estimate d Time to Market	Country	Comment  Respiratory indications; filed NDA 3/00; 800 mg QD;
Ketek (telithrom	Aventis	Ketolide	Filed 3/00 Est. launch 3/01	U.S.	first in ketolide class to reach market.

Ü

) [

		Ca	mpetitive Analysis	– Emergii	ng Competition
Product	Company	Class	Phase/Estimate d Time to Market	Country	Comment
Factive (gemiflox acin)	SKB	Quinolone	Filed 12/99 Est, launch 12/00	us	Superior to quinolones for MRSA; highly potent vs. RTI pathogens H. flu. M. cot, and S. pneumo and UTI pathogens E. coli and P. mirabilis, CRSP; potency > spar, trov, grepa and > moxi; activity vs. P. aeruginoso?; good atypical and mycoplasma coverage; intracullular penetration; low photo/CNS tox; 700 patient database
Sitafloxac in	Daiichi Seiyaku	Quinolone (IV only)	III II Est. launch 2002	Japan U.S., Europe	Very potent MRSA, pseudomonas and bacteroides activity; diarrhea, ALT, low WBC; will likely be target to severe rather than community infections
Ecenoflox acin	Chiel Foods	Quinolone	II Est. launch 2002	UK	Active against UTI and RTI pathogens; superior to lome and oflo vs. P. ceruginosa. Tiz = 14-19 hr; will likely be target to severe rather than community infections
CS-940	Sankyo	Quinolone	II Est. launch 2002	Japan	Active against G+i-; excellent activity against H. flu, c. jejuni, M. pneumo, and C. trachomatis, greater potency than cipro; t1a -7 hr, BA-80%
T-3811	Toyama/BM	Quinolone	I Est, launch 2005	Japan	Excellent potency and low toxicity
DC-756	Daiichi Pharma	Quinolone	Pre-clin Est. launch 2006	Japan	Low toxicity; in vitro potency ≥ trova, STFX & HSR- 903

Document 321-5

#### Unmet Needs

Overall unmet need in the anti-infective market is low. Resistance represents the largest unmet need, which will continue to evolve over time. Satisfaction with other product attributes, such as convenience, spectrum of activity, and tolerability/safety is quite high. Any improvements in these areas will be incremental and will offer little in the way of differentiation.

ABT-492 is one of the most active agents against the resistant organisms. It has indications that will have a low propensity for the development of resistance. ABT-492 will be developed to maximize any opportunities to shorten therapy. ABT-492 was chosen from hundreds of quinolones because of its potential to be well tolerated and safe in humans. ABT-492 will have few interactions with other drugs.

Unmet Need	Pipeline Impact
Activity against resistant organisms	Strep. pneumo, MRSA, and VRE represent most problematic pathogens although new quinolones/ketolides do well with most resistant Strep. pneumo strains; quinolone-resistant Strep. pneumo may develop; pseudomonas resistance is also increasing; resistance will likely continue to be a source of unmet need due to its dynamic nature.
Low propensity for resistance development	Given that most compounds in development are from classes of orugs already in use, this need is largely unmet. Unclear how quickly resistance will build to new classes of drug; gatifloxacin claims 8-methoxy functional group results in lower propensity for resistance
Convenience (duration/frequency)	Standard moves toward 5-7 days of therapy with QD dosing; may start to see 3-day therapies for some indications (AECB)
Increased tolerability	While some degree of unmet need exists, increasingly, agents (which have not been withdrawn) are reaching the marketplace with adverse event profiles that approach clinical insignificance; a very clean safety

	profile should be regarded as a necessary component rather than a
1	differentiating one Quinolones, macrolides, and ketolides all interact with other drugs to varying degrees; a potent drug with no interactions would be a benefit in
interactions	this market

#### Considerations

( i

> Product Usage: Physicians are likely to use ABT-492 for the sicker patients with the most difficult infections to treat. In the outpatient arena it will be used to treat community-acquired pneumonia and acute bacterial excerbations of chronic bronchitis in the older patients with an underlying illness. It will also be used in the hospital for the community-acquired pneumonia patient who requires hospitalization and for serious nosocomial infections.

> While many regard quinolones as agents that should be reserved for 2<sup>nd</sup> line use, their activity against H. influenzae and resistant Strep. pneumoniae (which current macrolides do not offer) have resulted in a high level of acceptance for empiric 1st line use. The improved safety profiles of several recent quinolones have facilitated their use as 1st line agents. Provided that ABT-492 is proven to have a benign safety/adverse event profile, it will likely receive usage in both 1st-line (non-severe) and 2<sup>nd</sup>-line (severe) infections.

Side Effects: The quinolone class has potential prolongation of the QT interval and other cardiovascular effects. There is also increased regulatory scrutiny due to recent quinolone withdrawals from international markets. ABT-492 has been evaluated in the standard in vivo models used to evaluate QT interval potentials of other antibiotics and has shown no evidence of increasing QT. Also, compared to marketed quinolones, preclinical studies show no evidence or no increase incidence of CNS drug concentration (ie. less potential for dizziness); phototoxicity;  $(\mathcal{L}_{\mathcal{A}_{i}}, \mathcal{L}_{\mathcal{A}_{i}}, \mathcal{L$ and liver toxicity.

Off-label use: It is difficult to predict at this time what off-label uses will be seen for this compound. Initial development will be for the more common respiratory, urinary tract, skin, and hospital infections. Other indications will be evaluated after the primary approval of this compound. Many of the secondary indications will get usage before we have regulatory approval.

COGS: The initial cost of goods is in \$6000/kg range, but will come down rapidly after the initial starting materials are determined. At time of launch ABT-492 will have a cost of goods in the \$1500/kg range which is competitive compared to other quinolones and other new antibiotics.

Dosing: Based on animal models and the in vitro activity of ABT-492 the dose for most oral indications will be in the range of 100 to 200 mg give once daily.

Development/Regulatory: Anti-infective compounds are well understood by regulatory agencies globally and they have clearly defined clinical development path and regulatory guidelines for reference. Abbott Laboratories has been in this arena for many years and has experience with the FDA and European regulatory agencies and so the hurdles to development are well known. ABT-492 has begun but not yet completed its first Phase I study in healthy volunteers.

Other Approaches: Because of the well defined development guidelines there are not many options. The major development options are in dosing regiments. ABT-492 is a very potent drug which has demonstrated rapid killing of pathogens in vitro and in vivo, and the development plan will attempt to shorten treatment durations to increase the competitive advantages of this activity.

į

Pricing: The community infection market is quite competitive from a pricing standpoint, with recent quinolones priced at approximately \$45 per 5-7 days of therapy. The pricing strategy will depend on strengths/weaknesses of the ABT-492 product label, the competitive landscape at launch, and the managed care environment, but current pricing assumption is parity for ABT-492 with respect to other quinolones.

CONFIDENTIAL

ABT - 510

# **Descriptive Memorandum**

February 2001

Abbott Laboratories

**ABT 510** 

C

1 (

þ Í

#### Overview

There is abundant evidence that primary tumor growth and metastatic progression require new blood vessel formation (angiogenesis). Tumors secrete inducer proteins including bFGF and VEGF that activate microvascular endothelial cells (EC) causing them to proliferate, migrate and organize into capillary structures. Activated endothelial cells also enhance malignant progression by producing signal molecules (cytokines) that inhibit programmed cell death (apoptosis) of tumor cells. Since anti-angiogenic therapy targets genetically stable endothelial cells, resistance typically seen following cytotoxic chemotherapy is not observed. Moreover, angiogenesis inhibitors should not have the intrinsic toxicity of anti-proliferative chemotherapy. Angiogenesis is also a feature of several other pathophysiologic states of large unmet medical need (macular degeneration, psoriasis, and arthritis, among others).

Angiogenesis sustains the growth and progression of tumors. Unlike chemotherapy or radiation, both of which can damage normal cells in addition to tumor cells, anti-angiogenic agents are hypothesized to prevent growth of new blood vessels and to disrupt critical tumor survival signals produced by EC. These agents may keep tumors in a dormant state for as long as the compound is administered and tumor regressions may occur. Proof of this principle has been demonstrated in pre-clinical models. Currently, at least thirteen compounds with anti-angiogenic activity in cancer are in various phases of clinical development, however few act directly and specifically on the angiogenesis process. Anti-angiogenesis drugs are not expected to replace or compete with current therapies. Instead, if these agents prove to be effective, it is believed that they will be used as supplemental therapy to prevent metastasis following surgery, cytotoxic chemotherapy or radiotherapy. As for cases where tumors have already metastasized, these agents could slow down disease progression and maintain "disease dormancy".

Thrombospondin-1 (TSP-1) was the first natural angiogenesis inhibitor to be discovered. TSP-1 is a large, multifunctional protein. TSP-1 rapidly inhibits EC migration and increases EC apoptosis through activation of caspase-3-like proteases. The normal tissue expression of TSP-1 limits inappropriate neovascularization, however it is transcriptionally activated by the tumor suppressor gene product p53. Therefore, TSP-1 is down-regulated and under-produced in p53 defective tumors. In rodent models, ectopic overexpression of TSP-1 inhibits the malignant phenotype as does direct administration of TSP-1 in the circulation. However, direct clinical use of TSP-1 is not feasible because of its scarcity, large size and multiple other biological functions.

The angiogenic activity of TSP-1 has been localized to the 50,000 MW N-terminal stalk region of this protein, and more specifically to the properdin (Type-1) repeats within this region. Although small synthetic peptides within this region have only weak antiangiogenic activity, it was discovered that a single D-amino acid replacement in a properdin region peptide led to an increase in activity of greater than 1000-fold. ABT-510 is a parenterally available nonapeptide. Although ABT-510 competes with TSP-1 for binding to the EC, the exact mechanism of antiangiogenesis is unknown.

ABT 510 is supplied for clinical use as a sterile solution in acetate salt in 5% dextrose. ABT 510 is soluble and stable in water.

In vitro, ABT 510 inhibits chemotactic VEGF/bFGF-stimulated migration of human microvascular endothelial cells (EC) with an IC50 of approximately 0.250 nM. This effect is EC specific. ABT-510 (10mg/kg/day subcutaneously) blocks VEGF-induced corneal vascularization in mice. It potently and selectively competes with TSP-1, binding the CD 36 receptor.

ABT 510 inhibits tumor progression in vivo. ABT 510(20mg/kg/day subcutaneous administration) inhibited tumor progression (78% growth inhibition at day 38) in a model of human breast cancer (MDA-MB-435) growing in the breast pads of nude mice. Dose dependent inhibition of B16F10 melanoma lung metastases was observed in a second murine model. ABT 526, a molecule highly similar to ABT 510 (which was not advanced into human trials because of concatemer formation) was administered to 23 companion dogs (25mg SQ BID) with sporadic cancers (head and neck carcinoma, lymphoma, sarcoma, etc) refractory to conventional chemotherapy. Surprisingly, 2 complete responses, 5 partial responses (>= 50% shrinkage) and 6 cases of disease stabilitization were observed.

Assays for toxicity, histamine release, hemolysis, T-cell function neutrophil migration, platelet aggregation, receptor (CEREP) screening and CNS function were unremarkable. ABT-510 produced no physiologically significant changes in cardiovascular or hemodynamic function in anesthetized dogs. In addition, there were no physiologically significant changes in clinical blood chemistry profiles or cardiac electrophysiologic function in response to ABT-510. Doses that were many times higher than the predicted efficacious concentration produced a moderate reduction in mean arterial blood pressure in conscious monkeys. ABT-510 was not mutagenic in the Ames assay. It is concluded therefore that ABT-510 has an excellent pre-clinical safety profile.

ABT-510 is currently in Phase I clinical trials. Because of its exceptional safety profile, normal volunteers are being dosed with ABT-510 to establish human safety and pharmacokinetic parameters. Review of these data will lead to a Go/NoGo decision for Phase II trials in the Summer of 2001.

The market

ŧ

Cytotoxic agents represent the largest, and fastest growing, class of oncology agents by sales volume. The following chart summarizes the value of the current oncology market. The market for products to treat cancer is changing rapidly. It is a growing market fueled by:

Increasing disease incidence

H 19553921

- New product entries
- New therapeutic paradigms
- A growing adjunctive market, which increases the number of patients eligible for chemotherapy
- Intense research and competition

The increase in the aging population in developed countries increases the incidence of cancer. The diagnosed cancer incidence and prevalence in seven major markets, including the U.S., France, Germany, Italy, Spain, U.K. and Japan are close to 3 million and 10 million respectively. The numbers are increasing steadily. Currently, about one-third of the new medicines in development are targeted against cancer.

Cancer is not a single disease, but includes more than 100 different disorders, which have at their core uncontrolled cell growth. Of these disorders, the cancer types that offer the greatest commercial opportunity include breast, colorectal, lung, ovarian and prostate (based on incidence/prevalence/unmet need). Treatment of breast, lung and prostate cancers account for more than 50 percent of the direct medical costs of cancer therapies. Other cancer types, specific to one or more of the major international markets, may provide niche opportunities. For instance, stomach (gastric) cancer is relatively common in Japan but not in the U.S. or Europe; similarly, liver cancer has a greater occurrence in Japan, Italy and Spain.

(\_ •

1 [

Depending on tumor type, cancer can be treated with surgery, radiation, chemotherapy (cytotoxic), hormonal therapy or a combination of any of these. For the purpose of this analysis, we will define the cancer market as chemotherapeutics and the adjunctive therapies used to counter the effects of chemotherapy and radiation therapy. The following charts summarize the global sales for these products.

## Global Sales by Market Segment (\$ MM)

				CA CD 106 109
	1996 Sales	1997 Sales	1998 Sales	CAGR '96-'98
	4.414	4.784	4,884	5.2%
Hormone	. 4.278	5,212	6,268	21.0%
Cytotoxic	3.367	3,651	4,166	11.2%
Adjunctive Total	12.059	13,647	15,318	12.7%

Source: Datamonitor

Sales by Region (\$ MM)

				04.05.400.400
	4006 Cales	1997 Sales	1998 Sales	CAGR '96-'98
	1996 Sales		7.422	15.5%
US	5,564	6,276		10.3%
Ex- US	6,495	7,370	7,896	10.070
LX- 00				

Source: Datamonitor

#### Chemotherapeutic agents

Cytotoxic therapies include classes such as alkylating agents, anti-tumor antibiotics, anti-metabolites and antimitotics (taxanes). These agents are toxic and demonstrate dose-limiting side effects. The commercial value of this segment is significantly understated, as most of the products are available in generic form.

The growth of the cytotoxic segment in the past three years has been driven primarily by the introduction of new, more effective and expensive therapies such as Taxol (paclitaxel/BMS), Gemzar (gemcitabine/Lilly), Taxotere (docetaxel/RPR) and Hycamtin (topotecan/SB). Utilization of these newer agents, however, appears to be dependent on the cost sensitivity of the local market. For example, secondary sources indicate that Taxol has recorded over 60% of its global sales in the US market alone and is prescribed with far less frequency in the more cost sensitive UK, German and French markets.

Most chemotherapeutic agents are indicated for just one or two cancer types, but get significant off-label use once approved. Up to 60% of an oncology product's use is potentially for off-label indications. Much of this use is driven by the publication of data and/or approvals in other countries.

#### Hormonal therapies

Of the top-selling drugs in each major geographical region, hormone therapies contribute approximately one-third of the sales ex-US and one-fourth in the US. Hormone therapies for the treatment of cancer include Lupron (leuprolide/TAP), Zoladex (goserelin/Zeneca), Nolvadex (tamoxifen/Zeneca) and other agents used to treat hormone responsive diseases such as prostate and breast cancer. These agents are generally administered chronically and have reduced side effects compared to cytotoxic therapies. Sales of this category are driven primarily by Lupron and Zoladex. The US market has become increasingly cost sensitive in the Medicare sector, which accounts for over 70% of Lupron sales.

Adjunctive agents

The availability of effective adjunctive agents also allows the cytotoxic chemotherapeutic agents to be administered at higher doses and/or more frequently, or used in a more palliative role, since the adjunctive therapies can reduce the impact of the chemotherapy on the patient's quality of life. Agents in this class include immunostimulants, anti-emetics and bisphosphonates. The growth of this market is linked to the growth of the cytotoxic market, as the increased use of cytotoxic agents drives an increased use in adjunctive therapy. The highest selling product in this class is Neupogen (filgrastim/Amgen) with 1998 sales of over \$1 billion.

#### Biologic Therapy

New therapies under development offer the promise of fulfilling several unmet needs in the treatment of cancer. Experts have predicted that in the future early therapy for breast cancer will be dominated by biological approaches, such as monoclonal antibodies (Herceptin/Genentech), which is widely thought to have strong market potential. Genentech recently reported strong second quarter sales of the product in the US of \$46.2 million, and it is estimated that if only half of US women with breast cancer who over-express this gene received Herceptin, sales would top \$600 million. In addition to monoclonal antibodies, other biological approaches include vaccines and gene therapy.

#### Future Trends

Emerging science in the past decade offers the potential to radically alter the paradigm for cancer therapy and presents opportunities for fundamentally new ways of approaching the disease. New therapies offer the promise of fulfilling several unmet needs in the treatment of cancer. These include matrix metalloproteinase inhibitors (MMPIs), continued expansion of biologics, photodynamic therapies (PDT), anti-angiogenics, and multiple drug resistance (MDR) modifiers. This market does not yet exist, though success of "cytostatic-like" treatments, such as hormonal therapies for prostate and breast cancer, suggests that the market potential for cytostatic agents could be significant.

#### Competition

The angiogenesis pipeline is very competitive, but this level of intensity is somewhat skewed by the large number of mechanistic approaches that are being claimed to demonstrate angiogenic activity. Furthermore, clear evidence of efficacy for these agents has not yet been demonstrated. For the purposes of this summary, only those compounds considered true anti-angiogenic compounds have been included. Companies with compounds in clinical development include Genentech, Entremed, Sugen, TAP, Magainin and Pharmacia Upjohn.

#### Angiogenesis Compounds in Clinical Development

	Indications	Company	Phase
Compound		Aetema	181
Neovastat	Solid tumors		11/111
RhuMab VEGF	Cancer	Genentech	
	Arthritis, psoriasis, CVR	lxsys	11
Vitaxin	Cancer	Sugen	11/111
SU-5416		TAP	ii
TNP 470	Cancer, arthritis	EntreMed/BMS	i
Thalidomide	Cancer		÷
Squalamine, squalus	Cancer	Magainin	1 .
		Ribozyme	!
RPI 4610	Cancer	NeXstar	1
VEGF antagonist	Cancer, retinopathy		i
Angiostatin/Endostatin	Cancer	EntreMed	<u> </u>

#### Unmet Needs

Cancer remains the second leading cause of death in the United States, Europe and Japan, and consequently, offers an attractive market opportunity for the pharmaceutical and biotechnology industries. This year about 563,100 Americans are expected to die of cancer, more than 1,500 people a day. In the US, 1 or 4 deaths is due to some form of cancer. In 1999, about 1,221,800 new cancer cases are expected to be diagnosed.

For most cancers, the level of physician satisfaction with current therapies is low. It has long been recognized by researchers, physicians, patients and family members that current treatment options may often be as devastating as the underlying disease.

Unmet needs in this market vary by turnor types and stages, with some turnors responding to treatment with better mortality and/or morbidity results than others. However, cancer is still treated as a terminal illness with significant shortcomings in present treatments. In general, unmet needs include:

Need	ABT-510 Attribute
Enhanced efficacy of therapeutic	Potential for enhanced efficacy
Reduced toxicity	Potential for reduced toxicity over current cytotoxic treatment
Improvements in drug administration Improved target delivery of cytotoxics	Unknown
and novel therapeutics Proven outcomes data	Quality of Life and Pharmacoeconomics to be assessed

#### Considerations

**9** [

• [

Product Usage: Physicians have indicated that they would use anti-angiogenic agents initially in their more refractory patients, as follow-on or add-on to current best therapy (chemo or surgical). With experience and clinical evidence, they would be willing to use these agents in earlier stages of the disease, where they perceived the greatest benefit to be. Anti-angiogenesis agents are regarded as a maintenance therapy to be used in early disease or after primary therapy as a prophylactic process to prevent the spread of malignancy. Of course, their ultimate use will depend on the benefit provided, which cannot be determined until clinical trials have been completed. Efficacy evidence in humans manifested by tumor response of the magnitude seen in the preliminary dog studies would stimulate tremendous enthusiasm in the oncology community.

Product Benefits/Efficacy. Physicians are looking for improvements in time to tumor progression and prevention of metastases with cytostatic agents. There is a great deal of enthusiasm for this mechanism in the scientific and lay audience. The concept is very intuitive. Products, such as ABT-510, that promise a clinical benefit without the usual toxic trade-offs associated with current chemotherapeutic agents, will be enthusiastically received by oncologists.

Side Effects The proposed safety profile of anti-angiogenic agents may enhance usage, as the dose limiting toxicity profiles of most of the other available agents has established a much lower hurdle for demonstrating a preferred profile. However, as chronic therapy, anti-angiogenic agents may have to demonstrate a cleaner profile than cytotoxic agents do to ensure compliance.

G.

į

Off-label use: Off label use accounts for between 30-60% of an oncology product's usage. Off-label use is driven by publication of clinical trial results in credible journals, listing in key compendia and/or a peer's experience with the product. Therefore, development spend for off-label use is considerably less than the spend required for regulatory approval of an indication. However, promotion of these off-label uses is limited.

Other indications: ABT-510 may be effective in other therapeutic roles, such as arthritic diseases and macular degeneration. These other indications may offer a commercial upside, through internal development or co-development/out-licensing opportunities.

Competition: While there are a relatively large number of angiogenesis inhibitors in development, it is unclear whether they will demonstrate a superior efficacy or side-effect profile vs. ABT-510. The mechanism of angiogenesis suggests that multiple anti-angiogenic approaches may be required to maximize the clinical benefit.

COGS: Initial estimates on finished cost of drug place it in the range of Lupron costs. Depending on final dosing requirements, the cost of this compound could become a significant obstacle. However, this will need to be considered in light of the pricing flexibility in the oncology market, where there is limited pricing sensitivity for products that are reimbursed. Any financial analysis will need to include royalty obligations to Northwestern University.

Dosing: There is still some uncertainty regarding the route of administration and feasible dosage forms for ABT-510. An "inconvenient" formulation leaves this product extremely vulnerable to competitors with more convenient dosage forms. A convenient dosage form, such as a monthly depot, will enhance product adoption over a less convenient form. However, the effect of the various dosage forms on product adoption will be dependent on the benefits the compound provides, side-effect profile and availability of competitive agents with more convenient dosage forms. For chronic therapy, convenience will play an important role in market penetration, given alternative agents. Although less convenient than oral therapy, parenteral therapy (depot, but not self-administered sub-cutaneous) is currently reimbursed by Medicare in the US. Over 60% of all cancer patients have Medicare as their primary healthcare coverage in the US.

Development/Regulatory: With a new class of compounds, there is not a clearly defined clinical development path or regulatory guidelines for reference. This hurdle is similar for all the competitive products, but increases the overall development risk profile for these agents. However, with several anti-angiogenic agents in late stage development, Abbott can learn from their experience.

Other Approaches: Other "cytostatic" approaches may present a competitive threat if they are used as substitutes. Due to the complexity of the pathogenesis of cancer, it is more likely that these agents will be used in combinations, but incremental benefits may become more difficult to demonstrate as the number of products and approaches multiply. This will require additional studies, as these other classes become part of standard cancer treatment. However, this threat is not unique to this compound.

*Pricing:* The treatment of cancer is expensive, so there is the potential for a great deal of pricing flexibility in this market. There is also an increasing emphasis on cost-effectiveness studies that will need to be addressed in the development plan.

CONFIDENTIAL JH 008192

Page 37 of 41

C

CONFIDENTIAL

**ABT - 518** 

# **Descriptive Memorandum**

February 2001

Abbott Laboratories

MMPI

(

#### Overview

Abbott's Matrix Metalloproteinase Inhibitor (MMPI) program represents a novel therapeutic class, with the potential to alter the way that cancer is treated by preventing or modifying disease progression and/or metastases. This more "chronic" approach to therapy has the potential to transform cancer into a disease that patients live with, much like the effect of HIV protease inhibitors on patients with AIDS. It also has the potential to expand the cancer market significantly by increasing the average length of treatment and expanding the pool of patients eligible to receive therapy.

The MMPs comprise a family of enzymes that degrade a wide range of matrix protein substrates. High expression of these enzymes occurs in cancer and is associated with the ability of tumors to grow, invade, develop new blood vessels and metastasize.

MMP inhibitors (MMPIs) may suppress the progression of tumors by several mechanisms:

- Suppress invasion/metastasis by blocking the membrane traversal and access to blood/lymphatic vessels
- Blocking the remodeling of extra-cellular matrix in the vicinity of primary tumors to prevent stroma-bound growth factors from stimulating tumor growth
- Blocking angiogenesis by preventing the proliferation and migration of endothelial cells and neovascularization of tumor.

Experimental evidence suggests that gelatinase A and gelatinase B are particularly important in tumor progression, consequently the project team has targeted gelatinase selective inhibitors for the treatment of cancer. Another reason for targeting highly gelatinase selective MMP inhibitors relates to the side effect profile exhibited by broad-spectrum agents like marimastat. Chronic administration of marimastat causes a dose-limiting side-effect characterized by severe joint pain and stiffness. Since these joint effects may be mediated by inhibition of other MMPs like fibroblast collagenase, highly gelatinase selective agents may be efficacious without producing dose-limiting side effects.

The MMP selectivity profile exhibited by ABT-518 distinguishes it from competitor's compounds. ABT-518 possesses sub-nanomolar inhibition potencies versus both gelatinase A and gelatinase B and is substantially more selective for the inhibition of the gelatinases over fibroblast collagenase than marimastat and prinomastat. Despite its high selectivity, ABT-518 demonstrates antitumor activity equal or superior to prinomastat. Inhibition of tumor growth is dose dependent in both syngeneic and xenograft models. ABT-518 is also effective in blocking vessel formation in a mouse model of angiogenesis. ABT-518 is a stable crystalline solid which can be synthesized in six steps (25% overall yield) from commercial starting material.

ABT-518 gives rise to sustained plasma concentrations following single oral dosing in monkeys, dogs and rats. Bioavailabilities range between 68 and 93% depending on formulation and species. Several metabolites are produced after repeated oral dosing of ABT-518, although their relative amounts varies with gender and species.

ABT-518 displays no meaningful effects in genotoxicity, cytotoxicity and ligand binding assays and its cardiovascular effects in dogs are unremarkable. ABT-518 produces no significant toxic effects in rats treated with 100 mg/kg/day over 28 days. Plasma concentrations generated by ABT-518 in these studies are at least 20-fold higher than those necessary to produce efficacy in cancer animal models. ABT-518 is therefore a compelling development candidate with the potential to

CONFIDENTIAL JH 008194

ı

demonstrate antitumor effects superior to the MMP inhibitors currently undergoing clinical trials. Phase 1 clinical trials in cancer patients began March 2001.

#### The market

Currently, cytotoxic agents represent the largest, and fastest growing, class of oncology agents by sales volume. The following chart summarizes the value of the current oncology market.

#### Global Sales by Market Segment (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
Hormone	4,414	4,784	4,884	5,000	5.2%
Cytotoxic	4,278	5,212	6,268	7,300	21.0%
Adjunctive	3,367	3,651	4,166	4,900	11.2%
Total	12,059	13,647	15,318	17,200	12.7%

Source: Datamonitor

1 [

1 {

#### Sales by Region (\$ MM)

			1000 0 1	4000 Coloc (set)	CAGR '96-'98
	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	
US	5.564	6.276	7,422	8,500	15.5%
	- • •	- •	7,896	8,700	10.3%
Ex-US	6,495	7,370	7,000		

Source: Datamonitor

Cytostatic agents have the potential to alter the way cancer is treated and presents opportunities for fundamentally new ways of approaching the disease. This cytostatic market does not yet exist, though success of more cytostatic "like" treatments, such as hormonal therapies for prostate and breast cancer, suggest that the market potential for cytostatic agents could be significant.

The ultimate commercial and clinical success of the MMPI will depend on the clinical benefit this product provides in key cancer types compared with current best therapy. These can be benefits provided by dosing this agent in addition to current therapy and/or as an alternative to best therapy, or as a new component of best therapy. All currently available products, including the market leaders such as Taxol, have significant shortcomings in their profiles.

However, as novel therapy, MMPIs will probably be adopted initially as add-on the current chemotherapy. As benefits are proven and clinical experience is gained, these agents may be used in earlier stages of cancer and/or in conjunction with surgery or radiation to prevent the progression of any microscopic disease that remains.

The clinical targets identified for this compound include late stage pancreatic cancer, late stage NSCL cancer (on-label), with late stage ovarian and breast cancer as additional cancer types where efficacy has been demonstrated, but not filed. Other cancer types this compound may be efficacious in include SCL, colorectal, bladder, stomach and prostate. Targets will be refined as we know more about this compound's in-vivo activity.

The following tables summarize the key marketed competitive products by indication (US data only):

Late Stage Breas	st
Product	Share
Cyclophosphamide/Cytoxan/BMS	18.7
Doxorubicin/Adriamycin/P&U	17.11
Docetaxel/Taxotere/RPR	16.25
Paclitaxel/Taxol/BMS	16.11
Trastuzumab/Herceptin/Genetech	11.26

Late Stage NSCL		
Product	Share	
Carboplatin/Paraplatin/BMS	50.32	
Paclitaxel/Taxol/BMS	44.14	
Vinorelbine/Navelbine/Glaxo	22.78	
Gemcitabine/Gemzar/Lilly	22.14	
Cisplatin/Platinol/RMS	11 28	

varian	
Share	
47.11	
45.42	
22.54	
9.14	
7.58	
,	
	47.11 45.42 22.54 9.14

Late Stage Par	creas	
Product	Share	
Gemcitabine/Gemzar/Lilly	78.5	
5-FU/Efudex/ICN Pharma	21.0	
Leucovorin/	10.7	
Cisplatin/Platinol/BMS	4.72	

#### Compounds in Development

The MMP inhibitor field is competitive. More than 30 firms have filed patents claiming small molecule MMP inhibitors over the past 5 years, and several companies have compounds in advanced clinical development. Abbott's compound may be 3<sup>rd</sup> or 4<sup>th</sup> to market and will have to demonstrate a competitive advantage to gain the share necessary to support the clinical development of this compound. Companies with compounds in advanced clinical development for the treatment of cancer include Agouron/Warner Lambert/Pfizer, British Biotechnology/Schering Plough and BMS and are listed below. Other companies are targeting this mechanism for arthritis.

MMPIs in Clinical Development for Cancer

# **Deposition Exhibit 1**

P's Exhibit 32 Part 5

Compound	Соправу	Comments	Phase
Marimistat	BritishBiotechnology/ Schering Plough	Broad spectrum, dose limiting toxicity. Activity seen in gastric cancer, but negative results in pancreatic.	111
Prinomastat	Agouron/ Warner Lambert/ Pfizer	Moderate gelatinase selectivity, dose limiting toxicity. May be dosing sub-optimally to avoid toxicity. Efficacy data not available.	111
BMS 275291	BMS	Broad spectrum, joint effects seen in Phase I studies.	11

Bayer recently dropped development of BAY 12-9566 due to concerns about potential toxicity. Recent results from a study with marimistat in pancreatic cancer, where adding marimistat to Gernzar resulted in no survival advantage, has led to speculation that MMPIs may be more applicable in less aggressive cancer types or earlier stages of the disease. Alternatively, it could be a reflection of the inability to examine higher doses of marimastat due to joint effects.

The joint effects produced by the compounds listed above almost certainly preclude their longitermuse, limit compliance and reduce optimal efficacy. Any MMP inhibitor that lacks these side effects will possess a substantial competitive advantage. The musculoskeletal effect produced by marimastar and prinomastat in cancer patients is typically described as arthralgia, myalgia and tendinitis, which occurs predominately in the upper limbs. While mild cases respond to analgesics, interrupting therapy for a period of approximately 2 weeks is necessary when the condition is less well tolerated.

Although Abbott's timing to market is not optimal, the shortcomings of the competitive products provide an opportunity for a compound with an improved SE or efficacy profile. Current animal models seem to predict Abbott's compound is superior to those currently in clinical trials, and has the potential to be best in class.

#### Product profile

€

1 1

£

The objective of a product profile at this time in the product's development is to provide a target for the types of attributes that will be required to be commercially successful. This profile is based on market research with oncologists and consultation with opinion leaders. This profile will continue to be refined as more is known about this product's profile, development of competitive products and the market continues to evolve.

	Base	Optimal
Efficaci	ART-518 alone or in combination with	Provides more man one or the
-	best therapy, provides at least one of	efficacy benefits outlined.

ş

) [

	the following benefits in at least one solid tumor type:  - Increased survival - Tumor regression - Improved quality of life - Increased time to tumor/disease progression	
Competitive advantage	ABT-518 will need to demonstrate a clinically significant advantage in efficacy (see parameters above) or additive synergistic activity with current/competitive agents or clinically significant advantage in side-effect profile relative to other MMPI agents.	Same
Administration	Convenient administration relative to competitive agents.	Same plus reimbursement in US market.
COGS	A finished cost of goods that is consistent with at least an 80% standard manufacturing margin.	A finished cost of goods that is consistent with at least a 90% standard manufacturing margin.

#### Marketing overview

Product Usage: Physicians have indicated that they would use MMPIs initially in their more refractory patients, as follow-on or add-on to current best therapy (chemo or surgical). With experience and clinical evidence, they would be willing to use these agents in earlier stages of the disease, where they perceived the greatest benefit to be. The MMPI was regarded as a maintenance therapy to be used in early disease or after primary therapy as a prophylactic process to prevent the spread of malignancy.

Product Benefits/Efficacy. Physicians are looking for improvements in time to tumor progression and prevention of metastases with cytostatic agents. The MMPI mechanism has more recently been implicated as having an even more active role in cancer pathogenesis, from preventing primary tumor growth to anti-angiogenic properties. Positive results from competitive agents, such as marimistat in gastric cancer, provides proof of principle for this mechanism.

Side Effects: The proposed safety profile of MMPIs (excluding joint toxicity) may enhance usage, as the dose limiting toxicity profiles of most of the other available agents has established a much lower hurdle for demonstrating a preferred profile. However, as chronic therapy, MMPIs may have to demonstrate a cleaner profile than cytotoxic agents do to ensure compliance. As the 3<sup>rd</sup> or 4<sup>th</sup> MMPI to market, SE hurdles will be even higher for this compound. As a critical Go/No Go decision point, the joint toxicity of this compound will be evaluated in an expanded Phase I multidose study.

Dosing: Discovery is currently targeting an oral dosage form. In general, oral therapies are acknowledged by physicians and patients as being more convenient to the patient. Chronic oral dosing may also reduce overall costs, as infusion support products and personnel would not be required, enhancing pharmacoeconomic evidence.

COGS: Initial estimates on finished cost of drug suggest that drug costs will not be significant for this compound

Off-label use: Off label use accounts for between 30-60% of an oncology product's usage. Off-label use is driven by publication of clinical trial results in credible journals, listing in key compendia and/or a peer's experience with the product. Therefore, development spend for off-label use is considerably less than the spend required for regulatory approval of an indication. However, promotion of these off-label uses is limited.

Competition: As the 3<sup>rd</sup> or 4<sup>th</sup> MMPI to market, Abbott's compound will need to demonstrate a meaningful clinical advantage over compounds that are in more advanced development. Strict Go/No Go criteria will determine if the MMPI can meet these hurdles. If they cannot be met, the compound will not move forward.

Development/Regulatory: With a new class of compounds, there is not a clearly defined clinical development path or regulatory guidelines for reference. This hurdle is similar for all the competitive products, but increases the overall development risk profile for these agents. However, with several MMPIs in late stage development, Abbott can learn from their experience.

Other Approaches: Other "cytostatic" approaches may present a competitive threat if they are used as substitutes. Due to the complexity of the pathogenesis of cancer, it is more likely that these agents will be used in combinations, but incremental benefits may become more difficult to demonstrate as the number of products and approaches multiply. This will require additional studies, as these other classes become part of standard cancer treatment. However, this threat is not unique to this compound.

Pricing: The treatment of cancer is expensive, so there is the potential for a great deal of pricing flexibility in this market. However, as an oral therapy in the US market, there may be additional downward price pressure for this agent. There is also an increasing emphasis on cost-effectiveness studies that will need to be addressed in the development plan.

Dosing: Discovery is currently targeting an oral dosage form. In general, oral therapies are preferred by physicians and patients because of the convenience to the patient. However, this form may not be the best choice for some people who already have certain digestive system symptoms (vomiting, diarrhea, or severe nausea), cannot swallow liquids or pills, or cannot remember when or how many pills to take. Additionally, in the US market there are several unique factors that currently do not favor oral therapies. Novel oral therapies are not currently reimbursed by Medicare, a significant payer for the oncology patient population. Also, 40-60% of a community oncologist's income is generated through the administration of IV drugs. An oral therapy would not be a source of revenue to the physician.

Clinical Studies

 $\overline{}$ 

) T

í

Clinical studies across a wide range of solid tumors will be initiated, including but not limited to breast cancer, non small cell lung cancer, ovarian cancer, pancreatic cancer, etc...

Final indications pursued will depend from the results of the phase II studies.

CONFIDENTIAL

# Farnesyltranserase Inhibitor

## **Descriptive Memorandum**

February 2001

**Abbott Laboratories** 

#### Overview

(

) [

The Ras genes were the first oncogenes of mammalian origin to be discovered. Intensive research over the last decade has led to the elucidation of the normal function of cellular Ras protein, the role of Ras mutations in oncogenic transformation, and the identification of molecular targets, such as the enzyme farnesyltransferase, for inhibiting Ras activity. Although farnesyltransferase inhibitors (FTIs) were initially designed with the intention of inhibiting the posttranslational prenylation, and hence function, of Ras, it is now becoming apparent that farnesylated proteins other than Ras (e.g., RhoB) are also critical for malignant growth and may be the relevant target for inhibition of farnesylation. While it remains controversial whether blocking Ras activity or altering the RhoB prenylation status is the actual function of an FTI, these agents, exemplified by ABT-839 and FTIs in the clinic, exhibit remarkable anticancer activity against a wide variety of tumors in preclinical models. The current FTI program is projected to reach DDC status in January, 2001.

Abbott evaluated one FTI, ABT-839, in normal volunteers, but decided to discontinue development of this drug due to its poor pharmacokinetic profile. Invaluable experience was gained, however, from both the preclinical and clinical studies with this compound. Abbott's second-generation series are novel structures that exhibit significantly improved potency and oral bioavailability.

There continues to be tremendous enthusiasm in the medical community and pharmaceutical industry for this mechanism of action. Farnesyltransferase inhibitors have demonstrated impressive antitumor activity in preclinical models with activity equivalent to or better than that achieved with conventional cytotoxic chemotherapy given at the maximal tolerated dose. These agents appear to inhibit angiogenesis and, consistent with this activity, minimal resistance has been observed in preclinical models. The potential also exists for synergistic activity in combination with cytotoxic chemotherapy.

#### The market

Cancer remains the second leading cause of death in the US, and consequently is an attractive market opportunity for the pharmaceutical/biotechnology industries. Approximately 40% of all Americans will develop cancer in their lifetime.

The worldwide cytotoxic and hormonal cancer therapies market is highly fragmented with only BMS and Zeneca holding a greater than 10% market share. Although the market is not concentrated, the field is highly competitive with more than 60 companies focused on the cancer research area. The growth of the oncology market is fueled by increasing disease incidence, new product entries, new therapeutic approaches, a growing adjunct therapy market that expands the number of patients eligible for chemotherapy, and intensified research competition. The data in Tables 1 and 2 summarize the value of the current oncology market. A great deal of uncertainty surrounds the concept of cytostatic treatment of cancer. Conceptually it may transform the way cancer is treated, allowing patients longer disease free survival and improved quality of life. However, at this point in development, this paradigm does not exist in cancer. Considering market, clinical and patient dynamics factors, breast, colorectal, prostate and non-small cell lung cancers are the most attractive targets for development.

(.

Table 1. Global sales by market segment (\$ MM)

Table 1. Globe	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est.)	CAGR '96-'98
		4,784	4.884	5.000	5.2%
Hormone	4,414	5.212	6.268	7.300	21.0%
Cytotoxic	4,278	3,651	4,166	4,900	11.2%
Adjunctive	3,367	•	15,318	17,200	12.7%
Total	12,059	13,647	10,010		

Source: Datamonitor

Table 2 Sales by region (\$ MM)

Table 2. Sales by region (4 mm)		1998 Sales	1999 Sales (est.)	CAGR '96-'98	
	1996 Sales	1997 Sales		8.500	15.5%
US	5,564	6,276	7,422	9,500	
Ey-US	6.495	7,370	7,896	8,700	10.3%

Source: Datamonitor

Cytostatic agents have the potential to alter the way cancer is treated and presents opportunities for fundamentally new ways of approaching the disease. This cytostatic market does not yet exist, though success of more cytostatic "like" treatments, such as hormonal therapies for prostate and breast cancer, suggest that the market potential for cytostatic agents could be significant.

The ultimate commercial and clinical success of the FTI will depend on the clinical benefit this product provides in key cancer types compared with current best therapy. These can be benefits provided by dosing this agent in addition to current therapy and/or as an alternative to best therapy, or as a new component of best therapy. All currently available products, including the market leaders such as Taxol, have significant shortcomings in their profiles.

However, as novel therapy, FTIs will probably be adopted initially as add-ons to current chemotherapy. As benefits are proven and clinical experience is gained, these agents may be used in earlier stages of cancer and/or in conjunction with surgery or radiation to prevent the progression of any microscopic disease that remains.

The clinical targets identified for this compound include late stage pancreatic cancer, late stage NSCL cancer (on-label), with late stage ovarian and breast cancer as additional cancer types where efficacy has been demonstrated, but not filed. Other cancer types this compound may be efficacious in include SCL, colorectal, bladder, stomach and prostate. Targets will be refined as we know more about this compound's in-vivo activity.

The following tables summarize the key marketed competitive products by indication (US data only):

Late Stage Breast

Product	Share	
Cyclophosphamide/Cytoxan/BMS	18.7	
Doxorubicin/Adriamycin/P&U	17.11	
Docetaxel/Taxotere/RPR	16.25	
Paclitaxel/Taxol/BMS	16.11	
Trastuzumab/Herceptin/Genetech	11.26	

Late Stage NSCL

Late Otago	· · · · · · · · · · · · · · · · · · ·
	Share
Product	50.32
Carboplatin/Paraplatin/BMS	44.14
Paclitaxel/Taxol/BMS	22.78
Vinorelbine/Navelbine/Glaxo	22.14
Gemcitabine/Gemzar/Lilly	11.28
Cisplatin/Platinol/BMS	

Late Stage Ovarian

	Share
Product Paclitaxel/Taxol/BMS Carboplatin/Paraplatin/BMS Topotecan/Hycamtin/SKB Dox SL/Doxil/Alza Cisplatin/Platinol/BMS	47.11 45.42 22.54 9.14 7.58

Late Stage Pancreas

Deaduct		Share
Product Cor	nzar/l illy	78.5
Gemcitabine/Ger	Dhorma	21.0
5-FU/Efudex/ICN	Pilalilia	10.7
Leucovorin/	DIAC	4.72
Cisplatin/Platinol/	BIVIS	

Emerging science within the past decade has radically altered the paradigm for cancer therapy and presents opportunities for fundamentally new ways of approaching the disease. Abbott has multiple discovery cytostatic targets, which may improve effective, but we are not alone: more than 200 compounds from other players are in development. The goal of cytostatic therapy is to improve quality of life, controlling the disease and transforming aggressive treatment to a chronic condition, which has been compared to the impact of protease inhibitors on the course of HIV.

#### Clinical Studies

C

1 1

) g

) [

! ?

Considering all the factors, market, clinical and patient dynamics, breast, colorectal, prostate and non-small cell lung cancer appear to be the most attractive targets for development. The development of cytostatic agents faces a number of challenges as regulatory agencies and physicians evaluate the new emerging paradigm of cancer therapy.

Despite the enormous medical need, drugs for chronic treatment/disease stabilization and improved quality of life for cancer patients do not yet exist. Correspondingly, animal models test efficacy that has not yet been validated as predictive of response in humans. Medical oncologists have historically depended on determination of maximum tolerated dose and response manifested by tumor shrinkage for cancer drug development. These parameters are not relevant to novel "cytostatic" agents. Combination with conventional cytotoxic drugs will be required in the near term and will have to be determined empirically. Intermediate and surrogate measures of biological response will have to be developed. Regulatory agencies are grappling with the same issues

#### Competition:

(

. .

ŧ

1 5

ŧ

#### Within Project Approach

	- Co-mound	Indication	Status of compound	Status of project
Company	Compound		Phase III	active
Janssen Pharmaceutica	R-11577 (A-251076)	Cancer (unspecified)	Phase II	active
Schering-Plough	Sch66336 (A-285622)	Cancer (unspecified)	Phase I (i.v.) abandoned	unknown
Merck	L-778123	Cancer (unspecified)		active
Bristol-Myers Squibb	BMS-214662	Cancer (unspecified)	Phase I	
	LB 42908	Cancer (unspecified)	preclinical	active
LG Chemical	quinuclidine derivatives	Cancer (unspecified)	preclinical	active
Rhone-Poulenc Rorer		Cancer (unspecified	preclinical	active
Plizer	unknown structure	Cancer (unspecified)	preclinical	active
Parke-Davis	unknown structure		preclinical	abandoned project
Roche	peptidomimetics	Cancer (unspecified)	preclinical	abandoned project
Eisai	peptidomimetics	Cancer (unspecified)		unknown
Banyu	FPP mimetic	Cancer (unspecified)	preclinical	active
ICIC	ISIS-2503 (ras antisense)	Cancer (unspecified)	Phase i	I drive

#### Within Therapeutic Area

	Selected Compounds	Company(ies)	Status
Approach		ISIS	phase i . :
antisense cytotoxic agents	psis 3521, ISIS, 5132 camptosar, Cl-980, farestron, Genzar, Hycamiin, indarubcin, Novantrone, Onconase, Capecitine, Tomudex	P&U, Warner-Lambert, Schering, Lilly, SKB, P&U, Immunex, Alfacell, Roche, Zeneca	most phase III
## - 1 <sup>1</sup> -1 <sup>2</sup>	targrefin, panretin, 5-azacytidine	Ligand, NCI	Ligand in phase II/III
differentiation . drug resistance modifiers	YX-710, 776C85, RMP-7, CT-2584	Vertex, Glaxo Wellcome, Alkernes, Cell Therapeutics	Vertex in phase II
gene therapy	Onyx-015, , MDRx1, GLI-328, IL-2, GV- 1301	Onyx, Introgen, Therion Biologics, Theragen, Genetic Therapy, Cyclacel, RPR Gencell, GeneMedicine, Tilan, etc	Restricted to accessible cancers. Most advanced: Phase VII
hormonal therapy	Zolodex, armidex, droloxifen, Oncolar, Rivizor, Casodex, rogletimide	Zeneca, Pfizer, Novartis, Janssen, US bioscience	most phase III
immunotherapy	Turicos, Gasoner, G		
antibodies	IDEC-Y2/In2B8, anti-HER2, anti EGFR	IDEC, Genetech, ImClone	IDEC recently approved, others phase III
	T 40 E 4 Bullio Deferre A	Roche, Schering, Chiron, Roche	phase III
cytokines	IL-12, IL-4, Proleukin, Roferon-A	Apolion, Therion, Progenics	phase I, II
vaccines	rV-gp100, Genevax, MGV		phase III
photodynamic	photofrin, promycin	QLT photo, Vion	phase II, III
radiation sensitizers	Neu-Sensamide, radinyl	Oxigene, Roberts	BBT in phase III
metalloproleinase inhibitors	marimastat, AG-3340, CGS-27023A	British Biotech, Agouron, Novartis, Bayer	see angiogenesis project
angiogenesis inhibitors	TNP-470, SU-5416, anti VEGF-mAb, thalidomide, DC101	TAP, Sugen, Genentch, Entremed, ImClone, etc	review for details

#### Competitive Analysis

ŧ

[

[

ć

;

The project is on par with others in the industry. While second generation Abbott compounds are not yet in clinic, all of the compounds from other companies that are in clinical trials have deficiencies. While the Schering compound has the best oral PK profile, it is not particularly potent. The Janssen compound is potent, but has a poor PK profile. The Merck compound exhibited QTc prologation and development has been stopped. The Bristol Myers Squib compound, BMS-214662, which is in phase I, is an *in vitro* submicromolar inducer of apoptosis in human tumor cells and appears to be the most potent inducer of apoptosis of the known FTIs. This compound could have a different mechanism of action from the classical FTIs and have its own liabilities. LG42908 from LG Chemical is potent FTI and has good oral bioavailability (F=91% in monkey), however, it's a CYP3A4 inhibitor and will have significant drug-drug interaction liabilities. Extensive preclinical pharmacology at Abbott has defined optimum parameters for a FTase inhibitor that may not be known to our competitors, or be achievable with the current generation of FTIs. Although not yet established, we anticipate that the Abbott compound will be improved over competitors' compounds with respect to potency, oral bioavailability, half-life, toxicity, efficacy, angiogenesis inhibition, and lack of resistance.

' C

1 I

CONFIDENTIAL

# DOPAMINE RECEPTOR AGONIST PROGRAM

### **Descriptive Memorandum**

February 2001

**Abbott Laboratories** 

#### D4 Agonists for Male Erectile Dysfunction

#### Scientific Overview

C

1 1

1 \$

ŧ

Male erectile dysfunction (MED) is defined as the "inability to maintain an erection sufficient for satisfactory sexual intercourse" (NIH Consensus Panel) and results from physiological (organic), psychogenic causes, or a combination thereof. This disorder is associated with decreased quality psychogenic causes, or a combination thereof. This disorder is associated with decreased quality psychogenic causes, or a combination thereof. This disorder is associated with decreased quality psychogenic causes, or a combination thereof. This disorder is associated with decreased quality psychogenic causes, or a combination thereof. This disorder is associated with decreased quality psychogenic causes, or a combination personal well been experienced family and social relationships. In 1999, and estimated 77 million men over the age of 40 (52% of men over 40 years-old) in the seven major pharmaceutical markets experienced some degree of MED, and the prevalence increases with age. Approximately 10-20% of patients have severe or complete MED, and the majority of the population suffers from moderate disease. While the introduction of Viagra has increased the diagnosis rate of MED in the U.S., 75% or more of patients do not seek treatment. However, as the "baby boomer" generation ages, MED will become a more prominent concern and a growing number of patients are likely to seek treatment.

Abbott's male erectile dysfunction program targeting D4 dopamine receptors represents a novel therapeutic approach to the rapidly growing male erectile dysfunction (MED) market. The current gold standard for the treatment of MED, Viagra, acts peripherally at the penile smooth muscle level to induce erection by modulating the levels of cGMP. In contrast, a selective D4 dopamine agonist will act in the brain at the sites necessary for initiation of a successful erection. Targeting the D4 receptors in brain offers the potential for efficacy in patients with MED that do not respond to Viagra (for example patients with diabetes). Additionally, targeting D4 receptors should not result in any cardiovascular adverse events unlike Viagra which can cause serious cardiovascular effects in patients who are on nitroglycerine-based medications. Since safety is of paramount importance for any life-style disorder like MED, a new agent that does not have any contraindications or warnings related to safety issues may be positioned to become the gold-standard therapy.

Evidence for the potential of a selective D4 dopamine receptor agonist for the treatment of erectile dysfunction includes:

- The non-selective dopamine receptor agonist apomorphine (Uprima<sup>TM</sup>) has been shown
  to be effective in phase III clinical trials, and has received scientific approval for market in
  the EU, for the treatment of MED. This validates the utility of dopaminergic agonists to
  facilitate penile erections in humans. However, the clinical development of apomorphine
  for the US market has been hampered by dose limiting side-effects (emesis and
  syncope).
- Studies at Abbott have established that the efficacy of apomorphine (penile erection) and side-effect (emesis) are mediated by different dopamine receptor subtypes. There are 5 known dopamine receptors. Abbott scientists have discovered that the selective activation of D<sub>4</sub> receptors can facilitate penile erection in animals, while the D<sub>2</sub> receptor appears to mediate the emetic effect of apomorphine. The discovery of a D<sub>4</sub> selective agonist maximizes the possibility to identify a compound with equivalent/superior efficacy to apomorphine but devoid of its side-effect liabilities.

PPD is currently screening the Abbott library of compounds to identify novel and proprietary D4 dopamine receptor compounds. Initial hits have been identified that are as potent as any known D4 dopamine receptor agonist. The strategy is to aggressively profile these hits for selectivity across the five different dopamine receptor subtypes and to ensure that selective agents are effective in a number of preclinical in vivo models of MED and have no emetic or cardiovascular side effects. The D4 dopamine receptor agonist program will be discontinued if selective D4 agonists do not achieve at least a 30-fold separation between efficacy in a model of MED and cardiovascular/emetic side effects.

Abbott has a competitive advantage in the race to exploit selective D4 dopamine receptor agonists for MED. A patent application covering the use of any selective D4 agonist for the treatment of MED has been filed and no other pharmaceutical company may have the range of preclinical models of efficacy and safety in addition to access to the clinical information gained from the development of apomorphine. Our molecular modeling group has facilitated advances in the design of selective D4 agonists.

#### Market Analysis

į

9 [

The introduction of Viagra combined with increased disease awareness resulted in the MED market in the US exploding from \$157MM in 1997 to an estimated \$726MM in 2000. Worldwide, this market has seen similar growth, and is estimated at \$500MM for ex-US for 2000. Viagra currently dominates the MED market, with more than \$1billion in sales in the \$1.3 billion worldwide market in 1999, and >95% of the MED prescriptions in the US. The market growth is expected to continue, with an estimated CAGR in the US of 17.9% (2000 – 2005), fueled by increased awareness of MED, expanded use to wider patient segments for relationship or performance enhancement, and the introduction of heavily promoted new agents. Downward pressure on growth will come from continued perceptions of safety concerns, the limited efficacy of Viagra IM, and out-of-pocket cost to patients.

Market drivers influencing the potential of a D4 dopamine receptor agonist include:

- Patient Awareness and Demand Viagra has built considerable awareness of MED. However, in the US, only 10-25% of current MED patients seek treatment for this disorder. Ex-US the percentage of patients seeking treatment is lower (10%). This is mainly due to the flack of DTC promotional campaigns in the ex-US markets. Further market expansion requires continued patient and physician education.
- Product Safety: There are growing patient and regulatory concerns regarding the safety
  of Viagra. While, physicians currently perceive Viagra<sup>TM</sup> to be safe, if used by the correct
  patients, there is significant concern regarding the concomitant use of nitrates for
  cardiovascular disorders with Viagra. Approximately 10% of Viagra patient deaths have
  been attributed to use of nitrates. Thus, there is an opportunity to eliminate this concern
  for physicians and to expand the market.
- Product Efficacy: In clinical trials Viagra allowed successful intercourse in about 50% of attempts. The limited and inconsistent efficacy of the product has resulted in patient dissatisfaction and discontinuation, thus creating a chance to drive Viagra quitters or switchers, as well as new patients, to new, more effective, MED products. The demonstration of efficacy in a broader population of MED patients might also influence physicians to try an alternative product prior to Viagra. The delay in onset (~1hr) and the variability in onset of action from patient to patient is an additional complaint about Viagra. Product features of a selective D4 agonist such as a more rapid onset of action or more reproducible onset will have a positive influence on the market opportunity for MED therapies.
- Additional Indications: Use of a D4 dopamine receptor agon in other indications such as "relationship enhancement" (female sexual dysfunction and age-related decline in male sexual performance) offers an opportunity to both expand the potential market to include women and non-MED sufferers, and reduce the embarrassment of MED for patients. Additional research is required to identify meaningful endpoints in this expanded indication. Initial studies conducted by Pfizer showed that Viagra<sup>TM</sup> was not effective to treat female sexual dysfunction.

Page 13 of 37

Ċ

1

į

The following tables summarize the key competitive activities in regard to marketed products and products in the development pipeline. To date there are no reports any other company targeting selective D4 agonists for the treatment of MED, although a number of companies do have activities in the dopamine receptor arena for other indications that could be re-focused to MED if they became aware of Abbott's insights into the D4 receptor.

#### A. Oral agents

Approach	Compound/Product	Company(ies)	Status
PDE5 inhibition	Sildenafil (Viagra™)	Pfizer	Marketed
DA receptor	Apomorphine (Uprima <sup>TM</sup> )	TAP	NDA filing withdrawn
Adrenergic	Phentolamine (Vasomax™)	Schering-Plough/Zonagen	NDA filing on hold (>1 year)
PDE5 inhibition	IC351 (Cialis <sup>TM</sup> )	ICOS-Lilly	Phase III
PDE5 inhibition	Vardenafil	Bayer	Phase II-III

#### B. Intranasal

Approach	Compound/Product	Company(ies)	Status
DA receptor	Nasal apomorphine	Nastech	Phase II

#### 🚁 4 -C - Intracavernosal agents

Approach	Compound/Product	Company(ies)	Status
EP receptor	PGE, (Caverjet <sup>TM</sup> , Edex <sup>TM</sup> )	Pharmacia, Schwarz Pharma	Marketed
VIP receptor/ Adrenergic	VIP-phentolamine (Invicorp <sup>TM</sup> )	Senetek	Marketed outside US
K channels	PNU 83757	Pharmacia	Phase II

#### D. Intraurethral agents

Approach	Compound/Product	Company(ies)	Status
EP receptor	PGE, (Muse <sup>TM</sup> )	Vivus, Abbott	Marketed

#### E. Topical

Approach Compound/Product		Company(ies)	Status	
EP receptor	PGE, (Alprox-TD; Topiqlan)	NexMed; MacroChem	Phase II and III	

MAR. 13. 2001 12:29PM

) C -

1,

ţ

Ī

. .

NO. 2199 P. 2/3

Brian J. Smith
Assistant Secretary and Divisional Vice President
Domestic Legal Operations
Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064

March 13, 2001

John Hancock Life Insurance Company
Investors Partner Life Insurance Company
John Hancock Variable Life Insurance Company
Attention: Stephen J. Blewitt
John Hancock Place
P.O. Box 111
Boston, MA 02117

Ladies and Gentlemen,

I have acted as counsel for Abbott Laboratories, an Illinois corporation (the "Company"), in connection with the Company's collaboration with John Hancock Life Insurance Company, a Massachusetts corporation, Investors Partner Life Insurance Company, a Massachusetts corporation, John Hancock Variable Life Insurance Company, a Delaware corporation (collectively, "John Hancock") pursuant to the Research Funding Agreement made as of March 13, 2001 (the "Research Funding Agreement"). Capitalized terms used herein without definition have the meanings assigned to them in the Research Funding Agreement.

In connection with the opinions expressed herein, I have made such examination of matters of law and of fact as I considered appropriate or advisable for purposes hereof. As to matters of fact material to the opinions expressed herein, I have relied upon certificates and statements of government officials and of officers of the Company. I have also examined originals or copies of such corporate documents or records of the Company as I have considered appropriate for the opinions expressed herein. I have assumed for the purposes of this opinion the genuineness of all signatures (other than those of individuals signing on behalf of the Company which are genuine), the legal capacity of natural persons, the authenticity of the documents submitted to me as originals, the conformity to the original documents of all documents submitted to me as certified, facsimile or photostatic copies, and the authenticity of the originals of such copies.

MAR. 178 2001 12:29PM

NO. 2199 P. 3/3

John Hancock Life Insurance Company Investors Partner Life Insurance Company John Hancock Variable Life Insurance Company March 13, 2001 Page 2

Based upon the foregoing, and subject to the qualifications and limitations stated herein, I am of the opinion that: (i) the Company is duly organized, validly existing and in good standing in the State of Illinois; (ii) the Company has the requisite corporate power and authority to execute, deliver and perform the Research Funding Agreement; (iii) the Research Funding Agreement has been duly and validly authorized by the Company, and duly executed and delivered by an authorized officer of the Company and constitutes a valid and binding legal obligation of the Company enforceable against it in accordance with its terms; (iv) the performance of the Research Funding Agreement by the Company does not constitute a breach or violation of its organizational documents or any other agreement or understanding, written or oral, to which the Company is a party or any existing law, statute, rule or regulation by which the Company is bound; (v) no consents or approvals of any court or governmental authority is required on the part of the Company in connection with the execution, delivery, and performance of the Research Funding Agreement; (vi) there is no litigation pending, or to my knowledge threatened, which calls into question the validity of the Research Funding Agreement.

My opinion expressed above is limited to the law of the State of Illinois and the federal law of the United States, and I do not express any opinion herein concerning any other law.

The opinion set forth herein is rendered only to you and solely for your benefit in connection with the above described transactions. This opinion may not be relied upon by you for any other purpose, or relied upon by any other person for any purpose, without my prior written consent.

Very truly yours.

Brian J Sm. H

## **Deposition Exhibit 2**

P's Exhibit NO

John Hancock.
FINANCIAL SERVICES

John Hancock Financial Services, Inc.

Bond and Corporate Finance Group

John Hancock Place Post Office Box 111 Boston, Massachusetts 02117 (617) 572-9624 Fax: (617) 572-1628 E-mail: sblewitt@jhancock.com

Stephen J. Blewitt Senior Managing Director

April 12, 2004

BY FAX (847) 937-6683 CONFIRMATION COPY BY U.S. FIRST CLASS MAIL

Mr. James L. Tyree Vice President, Global Licensing & New Business Development Abbott Laboratories 200 Abbott Park Road Abbott Park, IL 60064-6189

Re: Research Funding Agreement by and between Abbott Laboratories and John Hancock
Life Insurance Company, John Hancock Variable Life Insurance Company, and Investors
Partner Life Insurance Company, dated as of March 13, 2001

Dear Jim:

Pursuant to § 2.5 of the Research Funding Agreement by and between Abbott Laboratories and John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company and Investors Partner Life Insurance Company, dated as of March 13, 2001 (the "Agreement"), John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company and Investors Partner Life Insurance Company (collectively, "John Hancock") hereby give notice of the exercise of their right to inspect and audit all books and records of Abbot and of any Subcontractor of Abbott with respect to the following matters:

- 1. All Program Related Costs expended by Abbott during each Program Year;
- Compliance by Abbott with its obligations, under § 2.2 of the Agreement, to
  prepare and provide John Hancock with an Annual Research Plan, and to
  conduct the Research Program during each Program Year in accordance with
  the Annual Research Plan for such Program Year;
- 3. Compliance by Abbott with its obligation, under § 2.3 of the Agreement, to use Commercially Reasonable Efforts to conduct the Research Program in accordance with the requirements of § 2.3 of the Agreement;
- 4. Compliance by Abbott with its obligation, under § 4.3 of the Agreement, to substitute Program Compounds in accordance with the requirements of § 4.3 of the Agreement;

Campbell 2 2/30/07 cs

<sup>&</sup>lt;sup>1</sup> Unless otherwise specified herein, capitalized terms used in this letter and in the attached Schedule A shall have the same definitions as those set forth in the Agreement.

- 5. Compliance by Abbott with its obligation, under § 4.3 of the Agreement, to out-license or divest Ceased Compounds to third parties in accordance with the requirements of § 4.3 of the Agreement;
- 6. The stage of development and status of each Program Compound as of March 13, 2001; and
- 7. The current stage of development and status of each Program Compound.

Attached hereto as Schedule A is a preliminary list of those categories of books and records that John Hancock reasonably expects will be made available for its inspection and audit of these matters. The list is provided solely to assist Abbott in complying with this notice, and not by way of limitation. John Hancock requests that all books and records of Abbott and its Subcontractors pertaining to the above-identified matters be made available for its inspection and audit, regardless whether such books and records are described on Schedule A.

John Hancock's inspection and audit of the books and records of Abbott, as set forth herein, shall be conducted by Christopher Martinez, Brian Napper and other employees of the StoneTurn Group, LLP, a firm of independent auditors retained by John Hancock. The audit shall take place during normal business hours commencing on May 12, 2004, and continuing from day to day thereafter until completion, subject to adjournment as may be necessary to accommodate scheduling exigencies. In accordance with § 2.5 of the Agreement, John Hancock reserves its right to designate for copying, at its initial expense (but subject to reimbursement by Abbott in accordance with § 2.5 of the Agreement), any or all of the books and records of Abbott that are subject to its inspection and audit.

Please inform me before the close of business on May 5, 2004 of the specific location at which Abbott will make its books and records available for inspection and audit pursuant to this notice. Please also provide me with the name of the person who the StoneTurn Group's representatives should contact upon their arrival to begin their inspection and audit.

Thank you for your anticipated cooperation.

Very truly yours,

Stephen I. Blewitt

#### Attachment

cc: General Counsel (by fax, 847-938-6277; confirmation copy by mail)
Lawrence R. Desideri, Esq.
Peter E. Gelhaar, Esq.
Brian A. Davis, Esq.
Michael Arthur Walsh, Esq.

Blewitt

#### Schedule A

- All records and documents indicating expenditures made by Abbott related to any 1. compound that is now or ever was a Program Compound, including the following:
  - a. Abbott's standard policies and procedures related to accounting for project/program related expenditures;
  - b. Abbott's chart of accounts as relevant to accounting for project/program related expenditures;
  - c. Summary of costs/expenditures incurred by Program Compound by year delineating expenditures by nature (e.g., direct costs incurred by Abbott, subcontractor costs, allocated indirect costs, etc.);
  - d. Accounting framework for compiling the expenditures presented (i.e., whether cost assembled on an accrual or cash basis of accounting);
  - e. Identification of whether expenditures presented were capitalized or expensed under General Accepted Accounting Procedures ("GAAP") definitions;
  - f. Summary of the timing of expenditures for each Program Compound within each year presented;
  - g. Contracts or other governing documents and information related to all Research Program activities performed by Subcontractors;
  - h. Reconciliations of annual expenditures by Program Compound to the audited financial statements of Abbott;
  - i. Calculations, algorithms, and basis for all allocations included in the total expenditures by Program Compound by year;
  - i. Abbott standard policies and procedures related to allocation of indirect
  - k. Expenditure/Costs summaries and/or reports prepared in the normal course of managing the development of each Program Compound; and
  - 1. Underlying supporting records (e.g., timesheets, payroll records, purchase orders, invoices, etc.) for all expenditures made related to each Program Compound. -
- All records and documents discussing or evidencing the implementation and 2. conduct of the Research Program, including but not limited to:
  - a. Reports/Updates/Summaries prepared by Abbott in the normal course of managing the development of the Program Compounds;
  - b. Listing of all reports/updates/summaries typically prepared by Abbott during the normal course of developing an experimental pharmaceutical compound;
  - c. Minutes/Summaries/Notes from all management meetings in which any of the Program Compounds where reviewed or approved for further development funding;
  - d. Analysis and documentation supporting all forward looking projections of expenditures to be incurred for each Program Compound by year;

- e. Abbott policies and guidance as to the appropriate and/or required methods/approaches/procedures for conducting a research program for an experimental pharmaceutical compound;
- f. Abbott's internal approval framework for determining whether or not to continue to fund and develop an experimental pharmaceutical compound, including all relevant thresholds for approval along the compound development process; and
- g. Minutes/Summaries/Notes from all Abbott meetings regarding continued funding of product development for any Program Compounds.
- All records and documents concerning Abbott's obligations under § 4.3 of the 3. Agreement, including but not limited to:
  - a. Records identifying any and all Replacement Compounds;
  - b. Records identifying any and all Failed Early Stage Program Compounds;
  - c. Records identifying any and all Ceased Compounds;
  - d. All documents pertaining to Abbott's consideration or selection of any compound to replace any Failed Early Stage Program Compound;
  - e. Records identifying any and all compounds that Abbott held out as or considered to be "back up" compounds for the compounds that constituted the Program Compounds (i) on the effective date of the Agreement, and (ii) as of the end of each calendar year 2001 through 2003; and
  - f. All documents pertaining to the actual or attempted out-licensing or divestiture of any Ceased Compound.
- 4. All records and documents concerning the status of each Program Compound as of March 13, 2001 and currently, including but not limited to:
  - a. Reports/Summaries/Meeting Minutes which indicate the stage of development of each compound that originally constituted a Program Compound during the first calendar quarter of 2001;
  - b. Records describing the various stages into which Abbott generally categorizes the pre-clinical and clinical development of experimental pharmaceutical compounds;
  - c. Records indicating when each Program Compound reached each stage of pre-clinical or clinical development into which Abbott generally categorizes the pre-clinical and clinical development of experimental pharmaceutical compounds;
  - d. Reports/Summaries/Meeting Minutes which evidence the current status of . each Program Compound; and
  - e. Management Reports and/or other documents prepared in the normal course of business which indicate future prospects and development expectations for each Program Compound.

3678931vI

COMMUNICATION RESULT REPORT ( APR.12.2004 3:22PM ) \* \* \*

TTI JOHN HANCOCK

PAGE RESULT FILE MODE OPTION ADDRESS (GROUP) P. 5/5 ОK 126 MEMORY TX 918479376683

REASON FOR ERROR E-1) HANG UP OR LINE FAIL E-3) NO ANSWER

E-2) BUSY E-4) NO FACSIMILE CONNECTION

OND & CORPORATE FINANCE GROUP, T-57 .00 CLARENDON STREET **BOSTON, MA 02117** FAX: 617-572-1628/6454





To: James Tyree	From: Steve blew. H
Fax: 847 - 937 - 6683	Phone: 617-572-9624
Phones	# of Pages: 5 (including Court)
Date: 4/12/04	cc:
☐ Urgent ☐ For Review ☐ P	ase Comment     Please Reply     Please Recycle
Comments: This facsimile comments:	mication is strictly confidential and may be subject to

\* \* \* COMMUNICATION RESULT REPORT ( APR.12.2004 3:37PM ) \* \* \*

TTI JOHN HANCOCK

FILE MODE OPTION ADDRESS (GROUP) RESULT PAGE
427 MEMORY TX 918479386277 OK P. 5/5

REASON FOR ERROR E-1) HANG UP OR LINE FAIL E-3) NO ANSWER

E-2) BUSY E-4) NO FACSIMILE CONNECTION

BOND & CORPORATE FINANCE GROUP, T-57 200 CLARENDON STREET BOSTON, MA 02117 FAX: 617-572-1628/6454

JOHN HANCOCK FINANCIAL SERVICES



Urgent	☐ For Review	☐ Please Comment	☐ Please Reply	□ Please Racycle
Date: 4	11204	CCı		
Phone:	· · · ·	# of Pa	ges 5 lind	udent cover
Fax: 8	47-938-6d	7) Phone	<u>617-572-</u>	9624
To: Ge	neral Coun	sel From:	Stave of	Blue. H
		•		

<sup>•</sup> Comments: This facsimile communication is strictly confidential and may be subject to legal privileges. This communication is intended for the sale with t

\* \* COMMUNICATION RESULT REPORT ( APR.12.2004 4:22PM ) \* \* \*

TTI JOHN HANCOCK

FILE MODE OPTION ADDRESS (GROUP) RESULT PAGE

129 MEMORY TX 96172484000 OK P. 5/5

REASON FOR ERROR E-1) HANG UP OR LINE FAIL E-3) NO ANSWER

E-2) BUSY E-4) NO FACSIMILE CONNECTION

BOND & CORPORATE FINANCE GROUP, T-57 200 CLARENDON STREET BOSTON, MA 02117 FAX: 617-572-1628/6454





To: Br	ian Davis	From	: Stw	ب لها	m. H	
	17- 2-48-40	0 a Phon	es le l	J - Z"	12-96	24
Phone:		# of P	ages: 5	lind	udria	Lover
Date:	4/12/04	CC;				,
□ Urgent	☐ For Review	☐ Please Comment	□ Please I	Reply	☐ Pleas	e Recycle

<sup>•</sup> Comments: This facsimile communication is strictly confidential and may be subject to lend individuals. This communication is intended for the colours of the individuals?

\* COMMUNICATION RESULT REPORT ( APR.12.2004 4:25PM ) \* \*

TTI JOHN HANCOCK

PAGE ADDRESS (GROUP) RESULT FILE MODE OPTION P. 5/5 ОK 96172484000 130 MEMORY TX

REASON FOR ERROR E-1) HANG UP OR LINE FAIL E-3) NO ANSWER

E-2) BUSY E-4) NO FACSIMILE CONNECTION

OND & CORPORATE FINANCE GROUP, T-57 \_00 CLARENDON STREET BOSTON, MA D2117 FAX: 617-572-1628/6454





CONFIDENTIAL JHII 011890

To: Mil	nad Arthur L	NMSK	From:				m.H.	
Fax: (,(	7- 248-40	D &	Phone	<u> </u>	61	<u>1-5</u>	12-96	34
Phone:			# of Pa	gesi	5	(ind	udrig	Cover
Date:	4/12/04		CC:		,			· ·
☐ Urgent	☐ For Review	☐ Please Con	nment		Please	Reply	Plea	se Recycle
• Commen	ts: This facsimile	communicatio	n îs stri	ctly	confide	ential ar	nd may be	subject t

. ... :- :- :- tondad for the cole use of the individual(s) or

## **Deposition Exhibit 3**

P's Exhibit SD



To: Army E Potthoff/LAKE/PPRD/ABBOTT@ABBOTT, Kenneth D Stiles/LAKE/PPRD/ABBOTT@ABBOTT, Michelle L Campbell/LAKE/CORP/ABBOTT@ABBOTT, Richard F Pinto/LAKE/PPRD/ABBOTT@ABBOTT, Thomas E Woidat/LAKE/PPRD/ABBOTT@ABBOTT

cc: Subject: Meeting re Hancock audit w/Ken Wittenberg, Ken Stiles and Amy Potthoff⊜

The meeting scheduled for today at 4:00 p.m. regarding Hancock audit is to take place in Ken Stiles' office. Thank you.

Ken Wittenberg Abbott Laboratories Senior Counsel — Litigation Telephone: 847/ 938-8404 Facsimile: 847/ 938-6235

E-Mail: kenneth.wittenberg@abbott.com

Campbell 3

Kenneth D Stiles

Calendar Entry:

To: Richard F Pinto/LAKE/PPRD/ABBOTT Subject: Hancock Audit

04/20/2004 07:37 AM

Rich - I asked Ken Wittenberg to include you on the invite list, but from looking at this notice you were not invited. I'd like you to sit in. I recognize the timing is not good (with the Update package). We need to provide material to Hancock's auditors by May 12; out of this meeting should come some direction on gathering the necessary files, etc. I think Mischelle can handle some of the effort once we're clear on what the attorneys want pulled. Ken

Meeting		<b>)</b>	· King	
Subject:	Meeting re Hancock a Stiles and Arny Pottho	udit w/Ken Wittenberg, Ken	Location:	Ken's office
Begins:	Tue 04/20/2004	04:00 PM	Entry type:	☐ Meeting ☐ Appointment ☐ Ail Day Event ☐ Anniversary ☐ Reminder
Ends:	Tue 04/20/2004	05:00 PM		• • • • •
Chair: Sent by:	Kenneth A Wittenberg/ Becky L Haun/LAKE/C	LAKE/CORP/ABBOTT ORP/ABBOTT		
nvitations alrea		LAKE/PPRD/ABBOTT@ABI		tiles/LAKE/PPRD/ABBOTT@ABBOTT
Pencil In Mark Private Notify me	Others car	appear free to others.  nnot see any details about the sound see any details about the even	ils event. t.	
Categorize:				
Description:				••

Page 28 of 37

### **Deposition Exhibit 7**

P's Exhibit 58

#### WINSTON & STRAWN LLP

43 RUE DU RHONE 1204 GENEVA, SWITZERLAND

CITY POINT

ROPEMAKER STREET
LONDON, EC2Y BHT

333 BOUTH GRAND AVENUE LOS ANGELES, CALIFORNIA 10071-1543

LAWRENCE R. DESIDERI (312) 558-5960 Idesideri@wirators.com 35 WEST WACKER DRIVE CHICAGO, ILLINOIS 60601-9703

(312) 558-5600

FACSMILE (312) 558-5700

www.winston.com

200 PARK AVENUE NEW YORK, NEW YORK 19166-4183

21 AYENDE VICTOR HUGO 75118 PARIS, FRANCE

101 California Street San Francisco, California 94111-6894

> 1400 L STREET, N.W. WASHINGTON, D.C. 20006-3502

May 10, 2004

VIA FACSIMILE AND REGULAR MAIL Brian A. Davis, Esq. Choate, Hall & Stewart 53 State Street Boston, MA 02109-2804

Re:

Research Funding Agreement Between Abbott Laboratories ("Abbott") and John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company and Investors Partners Life Insurance Company (collectively, "Hancock") Dated March 13, 2001 (the "Agreement")

Dear Brian:

I am writing in response to your May 6, 2004 letter regarding Hancock's exercise of its audit right under the above Agreement. First, your assertion that thirty days prior notice should have been "more than adequate time" for Abbott to gather the necessary materials for the audit because Hancock mentioned an intention to exercise its audit right several months ago is meritless. To the exact contrary, Hancock's failure to exercise its audit right for at least several months after briefly mentioning the possibility of an audit had convinced Abbott that Hancock had likely abandoned the idea. Moreover, even had Abbott for some reason chosen to guess at Hancock's intentions regarding an audit (which it did not), it had no way of knowing what materials Hancock was seeking until it received Hancock's April 12, 2004 letter requesting the materials.

Second, because of the enormous breadth of materials Hancock seeks, Abbott in good faith requested a meeting with Hancock to explore whether less burdensome methods exist to provide Hancock with sufficient information to conduct its audit. Your assertion that Hancock cannot engage in such a meeting until it has a "better understanding of the nature and scope" of the materials Hancock requested strikes Abbott as disingenuous -- the very purpose of the meeting Abbott proposes is to provide Hancock with a better understanding of what is involved, and for Abbott to gain a better understanding of what Hancock truly needs, so that the parties can at least explore less burdensome alternatives.

For example, Hancock has requested each and every invoice, purchase order and payroll record relating to a project involving hundreds of millions of dollars of expenditures.

CONFIDENTIAL

ABBT 0000057

Campbell 7

#### WINSTON & STRAWN LLP

Brian A. Davis May 10, 2004 Page 2

Abbott has determined that just one small portion of just this one request (of a total of 30 requests by Hancock) involves approximately 24 boxes of timesheets alone. Abbott would like to explore whether gathering these types of volumes of these types of records is truly necessary. Accordingly, Abbott reiterates its request that Hancock meet with it to at least explore less burdensome alternatives.

Third, nothing in the Agreement confers upon Hancock the authority to unilaterally impose unreasonable deadlines upon Abbott. Given the scope and magnitude of Hancock's request, Abbott believes that Hancock's attempt to impose a thirty day deadline upon it is neither fair nor reasonable. That is why Abbott asked to meet to discuss a more realistic time frame to gather and produce the materials Hancock seeks. After having waited at least several months to even request an audit and identify the materials it wants to review, Abbott does not see how Hancock can in good faith now insist that Abbott comply with its audit request within a mere thirty days.

Abbott is in the process of gathering materials Hancock has reasonably requested. It intends to produce materials within a reasonable time. It will not, however, be producing materials on May 12, 2004. Abbott, once again, suggests that the parties discuss a mutually acceptable timeframe for the audit taking into account the scope and magnitude of the materials involved. As I informed you in my last letter, Abbott will be producing materials in Abbott Park,

Finally, thank you for the information concerning the StoneTurn Group and for the phone numbers of the individuals, whom you propose handle the audit. As I informed you on the phone, we were unable to locate any publicly available information regarding the Stone Turn Group on the internet. We will shortly be contacting the Stone Turn Group directly for more information, and after receiving the information, I will inform you if Abbott has any objection to the StoneTurn Group's participation in the audit.

Thank you for your anticipated cooperation.

Very truly yours,

Lawrence R. Decidori/KAB

Lawrence R. Desideri

LRD:da

cc: Peter E. Gelhaar, Esq.

CONFIDENTIAL

**ABBT 0000058** 

## **Campbell Deposition Exhibit 10** D's Exhibit MB



oc bec

06/03/2004 04:26 PM

Subject Hancock Audit

To wendrickx@247copies.com

Hì Jim -

Can we plan to meet at the RIC facility Tuesday afternoon, about 3:00? (I will e-mail the address, etc) They will have boxes ready, I do not know the count. I will need to have you pick up what you can turn around in a day. Depending upon the number of boxes, I would like you to return the originals to the RIC on Wed (and pick up another round) and the copies to Mundelein, etc.

I will have CD's coming also, and will need them to be printed, with the printouts going directly to Mundelein.

Let me know if this works,

Thanks

Michelle L. Campbell Litigation Paralegal Abbott Laboratories Dept. 324 Bldg. AP6D 100 Abbott Park Road Abbott Park, Illinois 60064 Phone: 847-937-1518 Fax: 847-938-6235

This communication may contain information that is legally privileged, confidential or exempt from disclosure. If you are not the intended recipient, please note that any dissemination, distribution, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer.

Campbell 10 2/20/07 45

## **Campbell Deposition Exhibit 11** D's Exhibit MC



"Wendrickx "
<Wendrickx@mail .247copies
.com>

To <michelle.campbell@abbott.com>

06/04/2004 12:10 PM

----- Original Message -----

Please respond to Wendrickx@mail.247copies.com> bcc Subject Re: Hancock - additional supplies - response requested

That works fine for me, just let me know what works best for you and I will make arrangements to meet you.

```
From: michelle.campbell@abbott.com
Date: Fri, 4 Jun 2004 11:48:05 -0500
>Not today, perhaps we can meet at Mundelein prior to the RIC on Tuesday?
>Mundelein is where the copies sets will need to be delivered, and then we
>can drop off the empty boxes.
>Let me know if this works.
>Thanks
>Michelle L. Campbell
>Litigation Paralegal
>Abbott Laboratories
>Dept. 324 Bldg. AP6D
>100 Abbott Park Road
>Abbott Park, Illinois 60064
>Phone: 847-937-1518
           847-938-6235
>Fax:
>This communication may contain information that is legally privileged,
>confidential or exempt from disclosure. If you are not the intended
>recipient, please note that any dissemination, distribution, use or >copying of this communication is strictly prohibited. Anyone who receives
>this message in error should notify the sender immediately by return
>e-mail , and delete it from his or her computer.
>"Wendrickx" <Wendrickx@mail.247copies.com>
>06/04/2004 11:43 AM
>Please respond to Wendrickx
         To:
                  <michelle.campbell@abbott.com>
```

Campbell 11

cc:

Skiller i State i State

```
Subject:
                         Re: Hancock - additional supplies - response
requested
>Hello Michelle, would you like me to bring the boxes this afternoon when I
        --- Original Message -----
>From: michelle.campbell@abbott.com
>Date: Fri, 4 Jun 2004 11:00:08 -0500
>>Hey Jim -
>>
>>Can I get 20 - 30 additional empty boxes from you? They can be charged
>>Hancock - Audit. I want to put the boxes picked up from records into the
>>same boxes that everything else will be in.
>>I will need box labels also:
>>Hancock Audit
>>Box # (1-100).
>>
>>I will need 4 labels per box and to start I will need numbers 1-100. They
>>should be 2-3 inch square labels and the text should be as large as will
>>fit and bolded. Please let me know the cost for the first 400 prior to >>creating any of these.
>>
>>Thanks
>>
>>Michelle L. Campbell
>>Litigation Paralegal
>>Abbott Laboratories
>>Dept. 324 Bldg. AP6D
>>100 Abbott Park Road
>>Abbott Park, Illinois 60064
>>Phone: 847-937-1518
>>Fax:
            847-938-6235
>>
>>
>>
>>This communication may contain information that is legally privileged,
>>confidential or exempt from disclosure. If you are not the intended
>>recipient, please note that any dissemination, distribution, use or
>>copying of this communication is strictly prohibited. Anyone who
>>this message in error should notify the sender immediately by return
>>e-mail , and delete it from his or her computer.
>>
>>
>>
>>
>>
>
>
```

Sent via the WebMail system at mail.247copies.com

# Campbell Deposition Exhibit 12 D's Exhibit MD

To Michelle L Campbell/LAKE/CORP/ABBOTT@ABBOTT



Frank R Pavelske/LAKE/PPRD/ABBO 06/10/2004 08:19 AM

cc wendrickx@247copies.com

bcc

Subject Re: RICs boxes, Hancock audit

We'll give Jim 80 today and send via Abbott delivery services another ~100 boxes hopefully this afternoon or first thing Friday morning.

I'll let you know the exact numbers after they're on the truck.

Frank Pavelske Compliance Section Manager Abbott Laboratories Research Information Center D-421/NP-J28 Phone: (847) 935-1230 FAX: (847) 937-9806 Frank.Pavelske@Abbott.com

This communication may contain information that is legally privileged and confidential or exempt from disclosure. If you are not the intended recipient, please note that any dissemination, distribution, use, or copying of this communication is strictly prohibited. If this message is received in error, immediately notify the sender via return e-mail or telephone at (847) 935-1230 and delete this e-mail.

Michelle L Campbell



Michelle L Campbell 06/09/2004 04:55 PM To: Frank R Pavelske/LAKE/PPRD/ABBOTT@ABBOTT

cc: wendrickx@247copies.com Subject: RICs boxes, Hancock audit

Hi Frank -

I agree with your idea to move the boxes to Mundelein. Jim, copied on the e-mail, can take approximately 80 boxes in his truck, when he comes by tomorrow. Or, if you would rather have the transferred by a RICs driver, that works too. For my purposes, this will assure that on Friday morning I will have plenty of boxes for review, either copies or originals.

We will continue to make copies and have the original boxes returned to the RIC asap. Please let me know how you want to handle transfer, I just need to assure that they are in Mundelein by Friday morning.

The warehouse is open from 6:30 - 2:30, for you reference.

Campbell 12



#### Thanks

Michelle L. Campbell Litigation Paralegal Abbott Laboratories Dept. 324 Bldg. AP6D 100 Abbott Park Road Abbott Park, Illinois 60064 Phone: 847-937-1518 Fax: 847-938-6235

This communication may contain information that is legally privileged, confidential or exempt from disclosure. If you are not the intended recipient, please note that any dissemination, distribution, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer.

# Campbell Deposition Exhibit 14 D's Exhibit ME



"Wendrickx "
<Wendrickx@mail .247copies
.com>

06/21/2004 09:22 PM

Please respond to <Wendrickx@mail.247copies.c om> To <michelle.campbell@abbott.com>

œ

bcc

Subject Re: Hancock Audit - Monday

Not a problem Michelle, sorry it toke me all day to get back but it has been a very busy day. I was not able to fit all the boxes in the van this morning and there were still a couple we were working on. I will deliver the remaing boxes from the weekend sometime on Tuesday before 2:00. If you need me to pick any more up on Tuesday or during the week just let me know.

Have a great day and I will talk to you soon,

Original Message
From: michelle.campbell@abbott.com
Date: Mon, 21 Jun 2004 09:13:01 -0500
>Hi Jim
>
>Hold off today on any pickups. I will let you know later, if we need any
>for tomorrow.
>
>I want to get an update from Ken, and let him know the costs.
>
>Thanks
>
>Michelle L. Campbell
>Litigation Paralegal
>Abbott Laboratories
>Dept. 324 Bldg. AP6D
>100 Abbott Park Road
>Abbott Park, Illinois 60064
>Phone: 847-937-1518
>Fax: 847-938-6235
>
>
>
>This communication may contain information that is legally privileged,
>confidential or exempt from disclosure. If you are not the intended
>recipient, please note that any dissemination, distribution, use or
>copying of this communication is strictly prohibited. Anyone who receives
>this message in error should notify the sender immediately by return
>e-mail , and delete it from his or her computer.
>
>
>
•
>
>
<b>&gt;</b>
<b>&gt;</b>
<b>&gt;</b>
>"Wendrickx" <wendrickx@mail.247copies.com></wendrickx@mail.247copies.com>
> MENGLICKY - MENGLICKYGHIGIT. 24 (CODIES. COM>

Campbell 14
2/20/07 (5

```
>06/21/2004 09:07 AM
>Please respond to Wendrickx
           To:
                     <michelle.campbell@abbott.com>
           cc:
           Subject:
                              Re: Hancock Audit - Monday
>Good morning Michelle, if I had to estimate I would say around 120,000 >blow backs ($12,000) and around 300,000 copies ($30,000) so around >$40,000. If you need a total just let me know and I can do that for you
>I will also be out there today around 10:00 or 11:00 to make a drop off >and possibly another pick up. We still have around 10 boxes left from the
>If there is anything you need just give me a call because I will be
>leaving the office shortly.
>Thank you,
>Jim
>----- Original Message -----
>From: michelle.campbell@abbott.com
>Date: Mon, 21 Jun 2004 07:42:31 -0500
>>Hi Jim - Thanks for the update. So I can update Ken as to costs, where
>>are we at so far? An estimate is fine.
>>
>>Thanks
>>
>>Michelle L. Campbell
>>Litigation Paralegal
>>Abbott Laboratories
>>Dept. 324 Bldg. AP6D
>>100 Abbott Park Road
>>Abbott Park, Illinois 60064
>>Phone: 847-937-1518
>>Fax:
               847-938-6235
>>
>>_
>>
>>This communication may contain information that is legally privileged,
>>confidential or exempt from disclosure. If you are not the intended
>>recipient, please note that any dissemination, distribution, use or >>copying of this communication is strictly prohibited. Anyone who
>receives
>>this message in error should notify the sender immediately by return
>>e-mail , and delete it from his or her computer.
>>
>>
>>
>>
>>
>>
>>
>>
>>"Wendrickx" <Wendrickx@mail.247copies.com>
>>06/18/2004 10:39 AM
```

```
>>Please respond to Wendrickx
>>
>>
>>
          To:
                   <michelle.campbell@abbott.com>
>>
>>
          Subject:
                           Re: Hancock Audit - Monday
>>
>>
>>Good morning Michelle, I just wanted to give you a follow-up on the
>>Hancock project. We will have 170 of the boxes copied for you by Monday >>morning. Along with the 170 boxes we also have 43 boxes of blow backs.
>>Giving you a total of 213 boxes for the beginning of next week. They
>have
>>informed me that they will have more CD's for me to pick up on Monday
>when
>>I drop off.
>>I estimate that there is still approx. 60-70 boxes still at the
>warehouse.
>> We will get to them starting on Monday.
>>Have a great weekend and I will talk to you soon.
>>
>>Jim
>>----- Original Message -----
>>From: michelle.campbell@abbott.com
>>Date: Fri, 11 Jun 2004 13:48:46 -0500
>>
>>>Jim - I am out on Monday so if you are going to mundelein please call
>>Daya
>>>prior to. Daya is at 847-937-3220
>>>
>>>Daya - if Jim is going to be at Mundelein, please call the emergency
>>>contact (whomever answers) on the PDF below and let them know that he
>>>be at the warehouse. The project is Hancock - and Jim may drop off and
>>>pick up.
>>>
>>>Thanks
>>>
>>>
>>>
>>>Michelle L. Campbell
>>>Litigation Paralegal
>>>Abbott Laboratories
>>>Dept. 324 Bldg. AP6D
>>>100 Abbott Park Road
>>>Abbott Park, Illinois 60064
>>>Phone: 847-937-1518
>>>Fax:
             847-938-6235
>>>
>>>
>>>
>>>This communication may contain information that is legally privileged,
>>>confidential or exempt from disclosure. If you are not the intended
>>>recipient, please note that any dissemination, distribution, use or
>>>copying of this communication is strictly prohibited. Anyone who
>>receives
>>>this message in error should notify the sender immediately by return
>>>e-mail , and delete it from his or her computer.
>>>
>>>_
```

```
>>>
>>>
>>>
>>>
>>>
>>>
>>>"Wendrickx" <Wendrickx@mail.247copies.com>
>>>06/11/2004 11:33 AM
>>>Please respond to Wendrickx
>>>
>>>
>>>
          To:
                  <michelle.campbell@abbott.com>
>>>
          cc:
>>>
          Subject:
                          Re: Hancock Audit
>>>
>>>
>>>Thank you, have a great weekend and I will talk to you next week.
>>>
>>>Jim
>>>----- Original Message -----
>>>From: michelle.campbell@abbott.com
>>>Date: Fri, 11 Jun 2004 10:28:08 -0500
>>>
>>>John - When do you plan on having your boxes dropped off at Mundelein?
>>>The
>>>>warehouse people want me to call prior to anyone dropping off or
>picking
>>>>up. (No hurry/ I just want to let them know)
>>>>Frank - I think we are on hold until the copies catch up , correct?
>RICs
>>
>>>
>>>is not planning a delivery at this point.
>>>>
>>>Jim - Please call me prior to your next trip (and any subsequent trips)
>>>to
>>>>Mundelein, so I can call the warehouse. If I do not answer, hit zero
>>and
>>>ask for Daya. I will let her know and she can find me or call the
>>>>warehouse if I am not around.
>>>>
>>>>Thanks again
>>>>
>>>>
>>>>Michelle L. Campbell
>>>>Litigation Paralegal
>>>>Abbott Laboratories
>>>Dept. 324 Bldg. AP6D
>>>>100 Abbott Park Road
>>>>Abbott Park, Illinois 60064
>>>Phone: 847-937-1518
>>>Fax:
             847-938-6235
>>>>
>>>>
```

```
>>>This communication may contain information that is legally privileged, >>>>confidential or exempt from disclosure. If you are not the intended >>>recipient, please note that any dissemination, distribution, use or >>>copying of this communication is strictly prohibited Anyone who
>>>receives
>>>>this message in error should notify the sender immediately by return
>>>e-mail , and delete it from his or her computer.
>>>>
>>>>_
>>>>
>>>>
>>>
>>>
>>>
>>>
>>>
>>>
>>>Sent via the WebMail system at mail.247copies.com
>>>
>>>
>>>
>>>
>>>
>>>
>>>
>>>
>>
>>
>>
>>
>>
>>
>>Sent via the WebMail system at mail.247copies.com
>>
>>
>>
>>
>>
>>
>>
>
>
>
>
>Sent via the WebMail system at mail.247copies.com
```

Sent via the WebMail system at mail.247copies.com

### **Deposition Exhibit 17**

P's Exhibit 59



>

Subject:

鳰

"Wendrickx" <Wendrickx@mail .247copies .com> To <michelle.campbell@abbott.com>

oc bcc

07/08/2004 10:41 AM

Please respond to Wendrickx@mail.247copies.com> Subject Re: Hancock audit

Yes, you are probably at \$80,000 for the entire project.

If there is anything else I can do for you please let me know.

```
Thanks,
Jim
         -- Original Message -----
From: michelle.campbell@abbott.com
Date: Thu, 8 Jul 2004 09:46:02 -0500
>Jim -
>Is this on top of the 2 invoices totaling about $56K?
>Michelle L. Campbell
>Litigation Paralegal
>Abbott Laboratories
>Dept. 324 Bldg. AP6D
>100 Abbott Park Road
>Abbott Park, Illinois 60064
>Phone: 847-937-1518
            847-938-6235
>Fax:
>This communication may contain information that is legally privileged, >confidential or exempt from disclosure. If you are not the intended
>recipient, please note that any dissemination, distribution, use or >copying of this communication is strictly prohibited. Anyone who receives
>this message in error should notify the sender immediately by return
>e-mail , and delete it from his or her computer.
>"Wendrickx" <Wendrickx@mail.247copies.com>
>07/07/2004 05:03 PM
>Please respond to Wendrickx
          To:
                   <michelle.campbell@abbott.com>
>
          cc:
```

Campbell 17

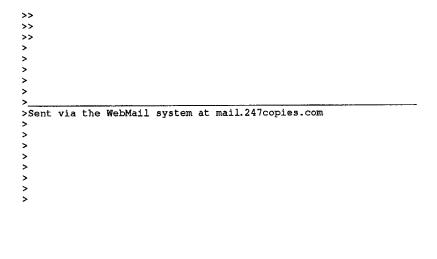
Re: Hancock audit

is Middle lesistis dicibile

id All to Salt bladde

```
>Not a problem, you have the two invoices from June. As of July you are >currently at 65 boxes copied and 37 boxes of blowbacks.
>65 boxes (2,500 @ 65 @.10)
                                      $16,250
>37 boxes bb (3,000 @ 37 @.10)
                                      $11,100
>I picked up an additional 28 boxes today 7/7.
>Cost of the 28 boxes
                                      $7,000
>(2,500 @ 28 @.10)
>As of today you are probably at $34,350.
>If there is anything else you need just let me know.
>Have a great day,
>Jim
>---- Original Message ---
>From: michelle.campbell@abbott.com
>Date: Wed, 7 Jul 2004 10:47:39 -0500
>>Hi Jim -
>>
>>Due to the growing size of this project, I will need daily updates as to
>>costs and box counts. A quick e-mail will suffice.
>>7/7/04 - P/U 10 boxes from RIC & Drop off 20 boxes at Mundelein. (10
>>boxes are blowbacks, 10 boxes are copies)
>>Cost to date 40.5K
>>If there is no activity on a work day, please e-mail as such.
>>
>>Sorry, but I need to keep a close watch on things, and its hard to do
>this
>>remotely.
>>
>>Thanks
>>Michelle L. Campbell
>>Litigation Paralegal
>>Abbott Laboratories
>>Dept. 324 Bldg. AP6D
>>100 Abbott Park Road
>>Abbott Park, Illinois 60064
>>Phone: 847-937-1518
>>Fax:
             847-938-6235
>>
>>_
>>
>>This communication may contain information that is legally privileged, >>confidential or exempt from disclosure. If you are not the intended
>>recipient, please note that any dissemination, distribution, use or
>>copying of this communication is strictly prohibited. Anyone who
>receives
>>this message in error should notify the sender immediately by return
>>e-mail , and delete it from his or her computer.
>>
```

animinanimina ka



## **Deposition Exhibit 18**

P's Exhibit 37



07/13/2004 02:30 PM

To <Wendrickx@mail.247copies.com>

CC

bcc

Subject Re: Hancock audit

Hi Jim -

We are on hold for now. I need a pick up for one small set of documents that they flagged, Thursday for the pick up would be best. (at the Park). Please confirm that the 8 boxes have been sent to Mundelein and that you do not have any other CD's to be printed.

#### Thanks

Michelle L. Campbell Litigation Paralegal Abbott Laboratories Dept. 324 Bldg. AP6D 100 Abbott Park Road Abbott Park, Illinois 60064 Phone: 847-937-1518 Fax: 847-938-6235

This communication may contain information that is legally privileged, confidential or exempt from disclosure. If you are not the intended recipient, please note that any dissemination, distribution, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail , and delete it from his or her computer.

"Wendrickx" < Wendrickx@mail.247copies.com>



"Wendrickx" <Wendrickx@mail .24</p> 7coples.com>

07/13/2004 11:36 AM Please respond to Wendrickx

To: <michelle.campbell@abbott.com>

Subject: Re: Hancock audit

Campbell 18
2/20/07 25

```
Michelle, just wanted to touch basis and make sure everything was going okay
on your project. Let me know if there is anything I can do. Have a great
day. Jim
----- Original Message -----
From: michelle.campbell@abbott.com
Date: Fri, 9 Jul 2004 13:32:49 -0500
>Please finish the 8 boxes and return the originals as normal. I will have
>more information on Monday. Have a great vacation!
>Michelle L. Campbell
>Litigation Paralegal
>Abbott Laboratories
>Dept. 324 Bldg. AP6D
>100 Abbott Park Road
>Abbott Park, Illinois 60064
>Phone: 847-937-1518
>Fax:
           847-938-6235
>This communication may contain information that is legally privileged,
>confidential or exempt from disclosure. If you are not the intended
>recipient, please note that any dissemination, distribution, use or >copying of this communication is strictly prohibited. Anyone who receives
>this message in error should notify the sender immediately by return
>e-mail , and delete it from his or her computer.
>
>
>
>"Wendrickx" <Wendrickx@mail.247copies.com>
>07/09/2004 01:25 PM
>Please respond to Wendrickx
                 <michelle.campbell@abbott.com>
         To:
         cc:
         Subject:
                         Re: Hancock audit
>Not a problem, I still have 8 boxes here at the office that we were
>working on, should I finish them up or stop on them completly.
>While I am gone if you can not get in touch with Joel feel free to contact
>Eddie he is one of the owner of 24/7.
>312-704-0247
>reeves@247copies.com
>I will be checking my e-mails while I am gone.
>Have a great day,
>----- Original Message -----
```

```
>From: michelle.campbell@abbott.com
>Date: Fri, 9 Jul 2004 09:07:53 -0500
>>Hey Jim -
>>Lets hold on the 30 for today. I need to talk to Ken on Monday. Also,
>>will you be bringing the file from Sue Kuras out to Mundelein today?
>>
>>Thanks
>>
>>Michelle L. Campbell
>>Litigation Paralegal
>>Abbott Laboratories
>>Dept. 324 Bldg. AP6D
>>100 Abbott Park Road
>>Abbott Park, Illinois 60064
>>Phone: 847-937-1518
>>Fax:
              847-938-6235
>>
>>
>>
>>This communication may contain information that is legally privileged, >>confidential or exempt from disclosure. If you are not the intended
>>recipient, please note that any dissemination, distribution, use or >>copying of this communication is strictly prohibited. Anyone who
>receives
>>this message in error should notify the sender immediately by return
>>e-mail , and delete it from his or her computer.
>>
>>
>>
>>
>>
>>
>>
>>
>>"Wendrickx" <Wendrickx@mail.247copies.com>
>>07/09/2004 06:34 AM
>>Please respond to Wendrickx
>>
>>
>>
            To:
                      <michelle.campbell@abbott.com>
>>
             cc:
>>
             Subject:
                                Re: Hancock audit
>>
>>Good morning Michelle, I will be picking up 30 more boxes today. After >>these boxes are copied are new total for the month will be $40,000 and a >>new grand total for the entire job (June & July) will be around $100,000.
>>I will see you later on today,
>>
>>Thanks,
>>Jim
>>----- Original Message -----
>>From: michelle.campbell@abbott.com
>>Date: Thu, 8 Jul 2004 09:46:02 -0500
>>>Jim -
```

SHASHAHAAA

```
>>>Is this on top of the 2 invoices totaling about $56K?
>>>
>>>Michelle L. Campbell
>>>Litigation Paralegal
>>>Abbott Laboratories
>>>Dept. 324 Bldg. AP6D
>>>100 Abbott Park Road
>>>Abbott Park, Illinois 60064
>>>Phone: 847-937-1518
>>>Fax:
             847-938-6235
>>>
>>>.
>>>This communication may contain information that is legally privileged, >>>confidential or exempt from disclosure. If you are not the intended
>>>recipient, please note that any dissemination, distribution, use or
>>>copying of this communication is strictly prohibited. Anyone who
>>receives
>>>this message in error should notify the sender immediately by return >>>e-mail , and delete it from his or her computer.
>>>
>>>
>>>
>>>
>>>
>>>
>>>
>>>
>>>
>>>"Wendrickx" <Wendrickx@mail.247copies.com>
>>>07/07/2004 05:03 PM
>>>Please respond to Wendrickx
>>>
>>>
                     <michelle.campbell@abbott.com>
>>>
            To:
>>>
            cc:
>>>
            Subject:
                              Re: Hancock audit
>>>
>>>Not a problem, you have the two invoices from June. As of July you are
>>>currently at 65 boxes copied and 37 boxes of blowbacks.
>>>65 boxes (2,500 @ 65 @.10)
                                         $16,250
>>>37 boxes bb (3,000 @ 37 @.10)
```

. Zidirikiliki ilikilik

```
>>>I picked up an additional 28 boxes today 7/7.
>>>Cost of the 28 boxes
>>>(2,500 @ 28 @.10)
>>>
>>>As of today you are probably at $34,350.
>>>
>>>If there is anything else you need just let me know.
>>>
>>>Have a great day,
>>>---- Original Message -----
>>>From: michelle.campbell@abbott.com
>>>Date: Wed, 7 Jul 2004 10:47:39 -0500
>>>
>>>>Hi Jim -
>>>>
>>>>Due to the growing size of this project, I will need daily updates as
>to
>>
>>>costs and box counts. A quick e-mail will suffice.
>>>>
>>>>Example -
>>>>7/7/04 - P/U 10 boxes from RIC & Drop off 20 boxes at Mundelein. (10
>>>boxes are blowbacks, 10 boxes are copies)
>>>>Cost to date 40.5K
>>>If there is no activity on a work day, please e-mail as such.
>>>>Sorry, but I need to keep a close watch on things, and its hard to do
>>>this
>>>remotelv.
>>>>
>>>>Thanks
>>>>
>>>>Michelle L. Campbell
>>>>Litigation Paralegal
>>>>Abbott Laboratories
>>>>Dept. 324 Bldg. AP6D
>>>>100 Abbott Park Road
>>>>Abbott Park, Illinois 60064
>>>Phone: 847-937-1518
>>>>Fax:
              847-938-6235
>>>>
>>>>
>>>>
>>>>This communication may contain information that is legally privileged,
>>>confidential or exempt from disclosure. If you are not the intended >>>recipient, please note that any dissemination, distribution, use or >>>copying of this communication is strictly prohibited. Anyone who
>>>receives
>>>>this message in error should notify the sender immediately by return
>>>e-mail , and delete it from his or her computer.
>>>>
>>>>
>>>>
>>>>
>>>>
>>>>
>>>
```

Sent via the WebMail system at mail.247copies.com

### **Deposition Exhibit 19**

P's Exhibit NS

JUL. 28. 2004 9:24PM CHOATE HALL & STEWART 6172484000

NO. 622 P. 1

**CHOATE** HALL & STEWARI

A PARTMERSHIP INCLUDING PROFESSIONAL CORPORATIONS

#### Fax Transmittal Sheet

PHONE FAX COMPANY RECIPIENT 312-558-5960 312-558-5700 Winstron & Strawn LLP Lawrence R. Desideri, Esq. NUMBER OF PAGES Karen Collari Troake FROM 2003799-0015 CLIENT NUMBER DATE July 28, 2004 TIME SENT **OPERATOR** PHONE (617) 248-5192

COMMENTS

**RETURN BY** 

Inter-office Mail

Hold for pick-up

This transmittal is intended only for the use of the individual or entity to which it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law, if the reader of this transmittal is not the intended recipient, or the employee or agent responsible for delivering the transmittal to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately.

CHOATE, HALL & STEWART | 53 State Street, Boston MA 02109 | t 617 248 5000 | 6617 248 4000 | www.choate.com

Campbell 2/20/07 45

ABBT0190564

JUL. 28. 2004 9:24PM

CHOATE HALL & STEWART 6172484000

NO. 622 P. 2

190:20005.7540**000** 

CHOATE, HALL & STEWART

lacktrian Parinerskip including professional comporations

Karen Cillah Troase Desect Dali (617) 242-5192 Baali KtroaseRChoate.com

EXCHANGE PLACE

BOSTON, MASSACHUSETTS 02:109-2804 INTERNE (617) 248-5000 • NAX (617) 248-4000

www.choatr.com

July 28, 2004

#### BY FACSIMILE

Lawrence R. Desideri, Esq. Winston & Strawn LLP 35 West Wacker Drive Chicago, Illinois 60601-9703

Dear Larry:

I am writing further to my voicemail messages of Monday, July 26 and earlier today and in reference to the inspection and audit currently being undertaken by Stone Turn Group LLP ("Stone Turn").

As you are aware, John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company and Investor Partner Life Insurance Company (collectively, "John Hancock") notified Abbott Laboratories ("Abbott") on April 12, 2004 that they were exercising their right to inspect and audit all books and records of Abbott and of any Subcontractor of Abbott, pursuant to § 2.5 of the Research Funding Agreement by and between Abbott and John Hancock dated as of March 13, 2001 (the "Agreement"). I have attached a copy of the original notice for your reference (the "Notice").

According to Stone Turn, although some documents have been made available, the majority of the documents identified in the Notice have not been made available; nor has Abbott provided any indication as to when the documents will be made available, despite repeated requests to do so. Moreover, it appears that none of the documents relating to cost and accounting information (described in Topic 1 of Schedule A to the Notice) or documents relating to Abbott's implementation of the Research Program (described in Topic 2 of Schedule A to the Notice) have been made available to the auditors. As I am sure you can appreciate, these categories of documents are critical to the audit.

3728720v1

<sup>&</sup>lt;sup>1</sup> Unless otherwise specified herein, capitalized terms used in this letter have the same definitions as those set forth in the Agreement.

JUL. 28. 2004 9:24PM CHOATE HALL & STEWART 6172484000

NO. 622 P. 3

Lawrence R. Desideri, Esq. July 28, 2004 Page 2

Accordingly, in an effort to ensure continued progress on the audit, please confirm when Stone Turn can expect to receive the following documents, which are listed in order of priority and in the order in which they should be made available:

- Documents described in Topic 1 of Schedule A.
- Documents described in Topic 2 of Schedule A.
- Documents described in Topic 4 of Schedule A.
- Documents described in Topics 5 and 6 of Schedule A
- Documents described in Topic 3 of Schedule A

With respect to Topic 3, it is our understanding that the majority of the documents produced to date relate to this topic. Please confirm whether there are any additional documents related to this topic, and, if so, when they will be made available.

I look forward to hearing from you.

Sincerely,

Karen Collari Troake

cc: Brian A. Davis, Esq.

Mr. Stephen G. Blewitt (By e-mail: sblewitt@hancock.com)
Mr. Christopher Martinez (By e-mail: cmartinez@stoneturn.com)
(All w/o encs.)

3728720v1

JUL. 28. 2004 9:25PM

CHOATE HALL & STEWART 6172484000

NO. 622

APR.12.2004 4:20PM

JOHN HANCOCK

No.429 F.2/5

John Hencock Furancial Services, Inc.

Bond and Corporate Finance Group

John Hangock Pace Post Office Sex 111 Baston, Massephusatis 021.17 (517) 572-9624 (EU) 572 1624

Stephen J. Blevilli Senjor Maraging Director

April 12, 2004

BY BAX (847) 937-6683 CONFIRMATION COPY BY U.S. FIRST CLASS MAIL

Mr. James L. Tyres Vice President, Global Licensing & New Business Development Abbott Laboratories 200 Abbott Park Road Abbott Park, IL 60064-6189

٦

Research Funding Agreement by and between Abbott Laboratories and John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company, and Investors Pariner Life Insurance Company, dated as of March 13, 2001

#### Dear Jim:

Presuant to § 2.5 of the Research Funding Agreement by and between Abbott Laboratories and John Hancock Life Insurance Company, John Hancock Vertable Life Insurance Company and Investors Partner Life Insurance Company, dated as of March 13, 2001 (the "Agreement"), Join Hancock Life Insurance Company, John Hancock Variable Life Insurance Company and Investors Partner Life Insurance Company (collectively, "John Hancock") hereby give notice of the examise of their right to inspect and smit all books and records of Abbot and of any Subcontractor of Abbott with respect to the following metters:

- 1. All Program Related Costs expanded by Abbott during each Program Year;
- 2. Compliance by Abboit with its obligations, under § 2.2 of the Agreement, to prepare and provide John Hanoock with an Annual Research Plan, and to conduct the Research Program during each Program Year in accordance with the Annual Research Plan for such Program Year,
- Compliance by Abbott with its obligation, under § 2.3 of the Agreement, to
  use Commercially Researable Efforts to conduct the Research Program in accordance with the requirements of § 2.3 of the Agreement;
- Compliance by Abbott with its obligation, under § 4.3 of the Agreement, to substitute Program Compounds in accordance with the requirements of § 4.3 of the Agreement;

Unless otherwise specified herein, capitalized terms used in this letter and in the attached Schedult A shall have the same definitions as those set forth in the Agreement.

CHOATE HALL & STEWART 6172484000 JUL. 28, 2004 9:25PM

NO. 622 P. 5

JOHN HUNCOCK 4:20PM APR.12.2004

P.3/5 NO.429

- 5. Compliance by Abbott with its obligation, under § 4.3 of the Agreement, to out-license or divest Ceased Compounds to third parties in accordance with the requirements of § 4.3 of the Agreement;
- 6. The stage of development and status of each Program Compound as of March 13, 2001; and
- The current stage of development and status of each Program Compound.

Attached hereto as Schedule A is a preliminary list of those entegories of books and records that John Hancock reasonably expects will be made available for its inspection and sudit of these matters. The list is provided solely to assist Abbott in complying with this notice, and not by way of limitation. John Hancock requests that all books and records of Abbott and its Subcontractors pertaining to the above-identified matters be made available for its inspection and sudit, regardless whether such books and records are described on Schedule A.

John Hancock's inspection and audit of the books and recends of Abbott, as set forth herein, shall be conducted by Christopher Martinez, Brisn Napper and other compleyees of the Sinns Turn Group, LLP, a firm of independent auditors retained by John Hancock. The audit shall take place during normal business home commencing on May 12, 2004, and continuing from day to day thereafter until completion, subject to adjournment as may be necessary to accommodate scheduling origenoiss. In accordance with § 2.5 of the Agreement, John Hancock reserves its right to designate for copying, at its initial expense (but subject to reimbursement by Abbott in accordance with § 2.5 of the Agreement), any or all of the books and records of Abbott that are subject to its inspection and audit.

Picase inform me before the close of business on May 5, 2004 of the specific location at Which Abbott will make its books and records available for inspection and sudit pursuant to this notice. Please also provide me wift fire name of the person who the StoneTurn Group's representatives should contact upon their arrival to begin their inspention and audit.

Thank you for your enticipated cooperation.

Very truly yours,

Stephen J. Blewitt

Blevite

Attachment

General Counsel (by fix, 847-938-6277; confirmation copy by mail) Lawrence R. Desideri, Esq. Peter R. Gelhaar, Esq. Brian A. Davis, Esq. Michael Arthur Walsh, Esq.

3679391+1

CHOATE HALL & STEWART 6172484000 JUL. 28. 2004 9:25PM

NO. 622 P. 6

JOHN HYNCOCK APR.12.2864 4:21PM

NO. 429 P.4/5

#### Schedule A

- All records and documents indicating expenditures made by Abbott related to any 1. compound that is now or ever was a Program Compound, including the following:
  - a. Abbott's standard policies and procedures related to accounting for project/program related expenditures;
  - b. Abbott's chart of accounts as relevant to accounting for project/program related expanditures;
  - o. Summary of costs/expenditures incurred by Program Compound by year delineating expenditures by mature (e.g., direct costs incurred by Abbott, subcontractor costs, allocated indirect costs, etc.);
  - d. Accounting framework for compiling the expenditures presented (i.e., whether cost assembled on an accrual or each basis of accounting);
  - e. Identification of whether expenditures presented were capitalized or. expensed under General Accepted Accounting Procedures ("GAAP") definitions;
  - f. Summary of the timing of expenditures for each Program Compound within each year presented;
  - Contracts or other governing documents and information related to all Research Program activities performed by Subcontractors;
  - h. Reconciliations of annual expenditures by Program Compound to the andited financial statements of Abbott;
  - Calculations, algorithms, and basis for all allocations included in the total expenditures by Program Compound by year,
  - Abbott standard policies and procedures related to allocation of indirect
  - costs; k Expenditure/Costs summaries and/or reports prepared in the normal course of managing the development of each Program Compound; and
  - L. Underlying supporting records (e.g., timesheets, payroll records, purchase orders, invoices, etc.) for all expanditures made related to each Program . Compound.
- All records and documents discussing or evidencing the implementation and 2 conduct of the Research Program, including but not limited to:
  - a. Reports/Updates/Summaries prepared by Abbott in the normal course of managing the development of the Program Compounds;
  - b. Listing of all reports/updates/summaries typically prepared by Abbott during the normal course of developing an experimental pharmaceutical ००मक्रकार्यः
  - Minutes/Summaries/Notes from all management meetings in which any of the Program Compounds where reviewed or approved for further development funding,
  - d. Analysis and documentation supporting all forward looking projections of expenditures to be incurred for each Program Compound by year,

CHOATE HALL & STEWART 6172484000 JUL. 28. 2004 9:26PM

P. 7 NO. 622

JOHN HANCOCK APR.12.2004 4:21PM

NO.429 P.5/5

c. Abbott politics and guidance as to the appropriate and/or required methods/sparozohes/procedures for conducting a research program for an experimental pharmacentical compound;

f. Abbott's internal approval framework for determining whether or not to continue to find and develop an experimental pharmacourical compound, including all relevant finesholds for approval along the compound development process; and

g. Minutes/Summaries/Notes from all Abbott meetings regarding continued funding of product development for any Program Compounds.

- All records and documents concerning Abbott's obligations under § 4.3 of the 3. Agreement, including but not limited to:
  - a. Records identifying any and all Replacement Compounds;
  - b. Records identifying any and all Bailed Harly Stage Program Compounds;
  - c. Records identifying any and all Ceased Compounds,
  - d. All documents pertaining to Abbott's consideration or selection of any compound to replace any Failed Early Stage Program Compound;
  - e. Records identifying any and all compounds that Abbott held out as or considered to be "back up" compounds for the compounds that constituted. the Program Compounds (i) on the effective date of the Agreement, and (ii) as of the end of each calendar year 2001 through 2003; and
  - All documents pertaining to the armal or attempted out-licensing or divestiture of any Ceased Compound.
- All records and documents concerning the status of each Program Compound as 4. of March 13, 2001 and currently, including but not limited to:
  - a, Reports/Summaries/Meeting Minutes which indicate the stage of development of each compound that originally constituted a Program Compound during the first calendar quarter of 2001;
  - Records describing the various stages into which Abbott generally categorizes the pre-clinical and obtained development of experimental Dystangoemical combounds?
  - c. Records indicating when each Program Compound reached each stage of pre-clinical or clinical development into which Abbott generally estagorizes the pre-clinical and clinical development of experimental pharmacentical compounds;
  - d. Reports/Summaries/Meeting Minutes which evidence the current status of each Program Compound; and
  - e. Management Reports and/or other documents prepared in the normal course of business which indicate future prospects and development expectations for each Program Compound.

3678931v1

Page 30 of 56

# Deposition Exhibit 20 P's Exhibit NT

AUG. 10. 2004 5:01PM

CHOATE HALL & STEWART 6172484000

NO. 248 P. 2

CHOATE, HALL & STEWART

a partypeship including professional cohporations

Karen Collari Troake Derect Dial: (617) 248-5192 Bhail: KTroake@Choate.com

EXCHANGE PLACE 53 STATE STREET

BOSTON, MASSACHUSETTS 02109-2804
TETEPEONE (617) 246-4000
WWW.CEDATE.COM

August 10, 2004

#### BY TELECOPIER AND REGULAR MAIL

Lawrence R. Desideri, Esquire WINSTON & STRAWN LLP 35 West Wacker Drive Chicago, Illinois 60601-9703

Re:

Research Funding Agreement by and between Abbott Laboratories ("Abbott") and John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company and Investors Partner Life Insurance Company (collectively, "John Hancock"), dated as of March 13, 2001 (the "Agreement")

Dear Larry:

I write in response to your letter of August 5, 2004. Your summary of the parties' dealings regarding the audit merits a response.

First, there is no question that John Hancock repeatedly offered to have its independent auditors come to Abbott's offices for the purpose of determining just what potentially responsive books and records Abbott has in its possession so that the parties could have an informed dialogue as to what materials would be most useful in conducting the upcoming audit. See, e.g., Letters from Brian Davis to Winston & Strawn dated May 6, 2004, May 11, 2004, and May 18, 2004. Abbott flatly rejected this offer. Your assertions regarding John Hancock's alleged lack of good faith are disingenuous at best in light of this rejection. Moreover, this rejection (and this alone) has resulted in Abbott's apparent inability to produce the requested documents in an efficient and timely manner. Again, we request that you permit the auditors access to Abbott's books and records to determine what documents are required to complete the audit so that the audit can proceed in the most efficient manner.

Second, the amount of time spent by the auditors in reviewing the documents provided to date says nothing about John Hancock's good faith conduct with regard to the audit. In fact, it

3733357v1

Campbell 20/07 45

CONFIDENTIAL
JHII 011334

AUG. 10. 2004 5:02PM

CHOATE HALL & STEWART 6172484000

NO. 248 P. 3

Lawrence R. Desideri, Esquire August 10, 2004 Page 2

demonstrates the auditors' good faith effort not to unnecessarily review every piece of paper until the universe of documents has been provided. In this way the auditors can determine what documents are most helpful to completing the audit and focus their time and energy reviewing and analyzing those documents. Undoubtedly Abbott's time and expense in relation to producing these particular documents might have been reduced had Abbott accepted John Hancock's offer to undertake a preliminary review of the relevant materials.

Third, as stated in my prior letter, the majority of the documents made available relate to Topic 3 in Schedule A to the April 12, 2004 letter. Specifically, they include FDA filings, study documentation, investigator packages, case reports, various scientific and technical studies and timesheets. None of these documents relate to Abbott's expenditures (as described in Topic 1 in Schedule A) or its projections for each Program Compound by year (as described in Topic 2 in Schedule A). In particular, the timesheets fail to identify anything other than time spent. There is no indication of the actual cost for the labor documented in these timesheets. Your letter says nothing to contradict this. Moreover, you have not indicated the scope of the remaining documents to be produced other than to cryptically state that the documents are ady provided "very well may constitute the 'majority' of the documents Hancock has requested." If this statement is correct, then it remains to be seen why Abbott cannot make available the remaining documents in less time than it took to gather the initial 750 boxes.

Fourth, as acknowledged by Abbott, it is John Hancock's right to conduct an audit pursuant to § 2.5 of the Research Funding Agreement. There is nothing in that agreement that prohibits John Hancock from requesting that documents be made available in a particular order to ensure that the audit is conducted in the most efficient manner possible. Again, Abbott's unwillingness to permit a preliminary review of the documents and engage in an informed discussion regarding those documents has resulted in John Hancock's requests to prioritize the production. Moreover, StoneTurn has repeatedly inquired as to when all the documents identified in Schedule A will be produced. These inquiries were made to Michelle Campbell at Abbott, who routinely stated that the inquiry would be passed on to others within Abbott, but no information has been provided in response. More recently, StoneTurn's calls to Abbott have gone unanswered. In light of this unresponsiveness, your suggestion that Abbott "continue to apprise the StoneTurn representatives as the volume of the materials available" is a hollow promise at best.

John Hancock is not prepared, or required, to postpone indefinitely the tate by which Abbott will comply with its obligation to make its books and records available for inspection under § 2.5 of the Agreement. Please notify me of a date certain falling on or before August 20, 2004, on which Abbott will permit John Hancock's auditors to come to Abbott's offices to

In the investigator packages there appear to be some references to the monies expended by Abbout to the doctors. However, this documentation is not complete, there are thousands of these packages and no summary of these expenditures has yet to be provided.

AUG. 10. 2004 5:02PM

CHOATE HALL & STEWART 6172484000

NO. 248 P. 4

Lawrence R. Desideri, Esquire August 10, 2004 Page 3

continue their work. Certainly by that date (which is over 120 days after Abbott first received official notice of John Hancock's intention to exercise its audit rights), Abbott will be able to make available the remaining documents. If the documents are provided on a rolling basis, we again request that they be provided in the following order of priority (from highest to lowest priority): (A) Topic 1(a)-(c), (h)-(i), (k); Topic 2(c)-(d), (f)-(g); Topic 3(d), (f); Topic 4(e); (B) Topic 1(e)-(f), (j); Topic 2(b); Topic 3(a), (e); Topic 4(b), (d); and (C) Topic 1(g), (l); Topic 2(a), (e); Topic 3 (b), (c); Topic 4(a), (c).

If, on the other hand, Abbott is not willing to allow the audit to continue in the requested time frame, John Hancock will have no choice but to take legal action to enforce its rights.

Sincerely,

Keun Collen Trocks in

Karen Collari Troake

cc: Peter E. Gelhaar, Esq. (by telecopier)
Michael S. D'Orsi, Esq. (by telecopier)
Brian A. Davis, Esq.
Michael Arthur Walsh, Esq.

3733357v1

CONFIDENTIAL
JHII 011336

AUG. 10. 2004 5:02PM

CHOATE HALL & STEWART 6172484000

NO. 248 P. 5

Lawrence R. Desideri, Esquire August 10, 2004 Page 4

bcc: Karen V. Morton, Esq. (by telecopier) Mr. Stephen J. Blewitt (by telecopier)

3733357vI

CONFIDENTIAL
JHII 011337

# **Campbell Deposition Exhibit 21** D's Exhibit MF

#### WINSTON & STRAWN LLP

43 RUE DU RHONE 1204 GENEVA, SWITZERLAND

CITY POINT I ROPEMAKER STREET LONDON, ECZY SHT

LOS ANGELES, CALIFORNIA 90971-1543

333 SOUTH BRAND AVENUE

LAWRENCE R. DESIDERI (312) 558-5960 Idealded @wineton.com

35 WEST WACKER DRIVE CHICAGO, ILLINOIS 60601-9703

(312) 558-5600

FACSIMILE (312) 556-5700

water wington con-

August 5, 2004

200 PARK AVENUE HEW YORK, HEW YORK 18166-4183

and all all all the state of the

21 AVENUE VICTOR HUGO 75116 FARIS, FRANCE

101 CALIFORNIA STREET SAN FRANCISCO, CALIFORNIA MITI-SEDA

1400 L STREET, M.W. WASHINGTON, D.C. 20005-3502

#### VIA FACSIMILE AND U.S. MAIL

Ms. Karen Collari Troake Choate, Hall & Stewart 53 State Street Boston, MA 02109-2804

Re:

Research Funding Agreement Between Abbott Laboratories ("Abbott") and John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company and Investors Partners Life Insurance Company (collectively, "Hancock") Dated March 13, 2001 (the "Agreement")

Dear Ms. Troake:

( ·

I write in response to your letter of July 28, 2004, which makes a number of inaccurate assertions concerning Abbott's production of records to date in response to Hancock's audit request, and now demands, for the first time, that records be made available in a certain order. Let me begin by reminding you of the history of what has transpired here so that Hancock can fully appreciate Abbott's position.

As you know, Abbott has been concerned from the very outset regarding Hancock's good faith in conducting its audit. Specifically, Abbott repeatedly informed Hancock prior to the audit that the enormous breadth of materials sought by Hancock is difficult to reconcile with a true audit, rather than a fishing expedition to attempt to gain leverage or advantage in the parties' pending litigation over Hancock's refusal to make further payments under the Research Funding Agreement. Not only does Hancock's request encompass a broad range of obligations that have never been in dispute between the parties, the audit request seems calculated to impose an unnecessary and unreasonable burden upon Abbott.

In light of the above, Abbott in good faith repeatedly requested a meeting with Hancock prior to the audit to at least explore whether less burdensome methods existed to provide Hancock with sufficient information to conduct its audit and whether requiring Abbott to produce reams upon reams of certain types of documents truly was necessary. For example, in my May 10, 2004 letter to Mr. Davis I explained:

CONFIDENTIAL

Campbell 21

**ABBT 0000125** 

#### WINSTON & STRAWN LLP

É

Ms. Karen Collari Troake August 5, 2004 Page 2

[H]ancock has requested each and every invoice, purchase order and payroll record relating to a project involving hundreds of millions of dollars of expenditures.

Abbott has determined that just one small portion of just this one request (of a total of 30 requests by Hancock) involves approximately 24 boxes of timesheets alone. Abbott would like to explore whether gathering these types of volumes of these types of records is truly necessary. Accordingly, Abbott reiterates its request that Hancock meet with it to at least explore less burdensome alternatives.

Tellingly, Hancock refused this good faith request to meet prior to the audit and has refused to limit its request in any way whatsoever.

Within approximately ninety days of receiving Hancock's audit request, Abbott has produced over 750 boxes of materials that Hancock insisted it needed — which approaches two million pages of materials. Abbott has incurred approximately \$100,000 in copying costs alone in making these materials available to Hancock. Hancock's conduct upon receiving these massive amounts of materials has only further heightened Abbott's concern regarding Hancock's good faith in conducting the audit.

Having imposed upon Abbott the burden of producing over 750 boxes of documents to date, the Stone Turn Group spent a mere 95 hours reviewing the documents. This translates into approximately 20,000 documents per hour. Of the almost two million pages of materials to date that Hancock insisted were so imperative to its audit that it could not even explore whether less burdensome alternatives might exist to Abbott producing the materials, Hancock's experts have copied a grand total of 900 pages. Hence, Hancock has plainly forced Abbott to go to the burden and expense of making materials available that Hancock had no intention of meaningfully reviewing.

With this background, I turn to the assertions contained in your letter. First, you state (without explanation) that "although some documents have been made available, the majority of the documents identified have not been made available..." The "some documents" you refer to are 750 boxes of materials that Hancock insisted it needed and that Abbott produced within approximately ninety days. Moreover, these documents very well may constitute a "majority" of the documents Hancock has requested.

Second, you assert that none of the cost and accounting information described in Topic 1 of Schedule A to Hancock's Notice, or documents relating to Abbott's implementation of the Research Program, have been made available to StoneTurn. This assertion is inaccurate. Abbott has produced volumes of requested materials relating to costs of the Research Development Program including, for just one example, approximately 20 boxes of documents specifically requested in Topic 1 of Schedule A. Moreover, Abbott has produced hundreds of boxes specifically evidencing the implementation and conduct of the Research, including but not limited to, clinical programs.

CONFIDENTIAL

#### WINSTON & STRAWN LLP

Ms. Karen Collari Troake August 5, 2004 Page 3

Third, your unexplained statement that Hancock understands that the "majority" of the documents made available to date relate to Topic 3 of Schedule A — which requests records concerning Abbott's obligations under § 4.3 of the Agreement, including Replacement Compounds, out-licensing and divestiture — is not consistent with Abbott's understanding. Perhaps you could elaborate upon the basis for this perception on Hancock's part and we can then discuss the matter.

Fourth, your letter attempts to dictate, for the first time, that records be made available in a specific order. Nothing in the Agreement permits Hancock to dictate unilaterally the order in which Abbott must make available requested materials. Moreover, Abbott finds this demand by Hancock to be further demonstrative of Hancock's lack of good faith in light of Hancock's repeated refusal to meet with Abbott prior to the audit to explore, among other things, prioritizing Hancock's massive request in an effort to reduce the burden upon Abbott. Having been forced by Hancock for months to gather huge volumes of records indiscriminately, Abbott will continue to produce the records in the order they are gathered.

Fifth, your letter refers to Topics 5 and 6 of Schedule A. The Schedule A Hancock provided to Abbott does not contain a Topic 5 or 6, nor does the Schedule A attached to your letter. Please let us know what you are referring to as Topics 5 and 6.

Finally, you inquired as to when additional documents would be available. As you might imagine, Abbott did not anticipate Hancock completing its review of almost two million documents in a mere 95 hours. In any event, as I believe Abbott has informed StoneTurn Group directly, Abbott is, and has been, in the process of gathering additional materials and will be making these materials available on a rolling basis as they are gathered. You should be aware that portions of the remaining materials Hancock has requested were not created or maintained separate from Abbott's non-Research Program activities and will need to be sorted and or redacted prior to production. This will slow down the production of these materials to some degree.

Abbott presently expects to have additional materials available for inspection next week. I suggest that Abbott continue to apprise the StoneTurn representatives of the volume of materials available so that they can schedule their reviews accordingly.

Please contact me if you like to discuss these matters further.

Very truly yours,

Lawrence R. Desideri

LRD:da

cc: Peter Gelhaar

CONFIDENTIAL

ABBT 0000127

# **Deposition Exhibit 30**

P's Exhibit OG



To "Michelle L Campbell" <michelle.campbell@abbott.com>

cc "Mark Hair" <mhair@stoneturn.com>, "Chris Martinez" <cmartinez@stoneturn.com>

bcc

Subject Copies of Documents Flagged Today

#### Michelle,

Thanks for arranging for the review of documents today. As I informed Yolanda, I tagged a number of documents for copying. Further, as I indicated in the couple of voice messages I left you earlier, we need to get these copies delivered to StoneTurn on Monday AM. I assume this doesn't present a problem, but if it does, we can bring in an outside firm to handle the job. As I indicated in my messages to you, please let me know today if you would like StoneTurn to arrange for copying, otherwise, we may not be able to accomplish it and guarantee delivery by Monday AM.

In any event, please ship the document copies to:

Mark Hair StoneTurn Group LLP 2121 N. California Blvd., Ste 290 Walnut Creek, CA 94596 (925)974-3377

Also, if you could include in that shipment the copies of the documents we requested back in July, and re-requested at our December 17<sup>h</sup>, 2004 meeting, I'd appreciate it.

Further, as I understand that all of the Abbott documents responsive to John Hancock's request for documents will be available by January 31, 2005, Mark Hair and I will plan on returning to your facility to review documents on that date. Please confirm that such a review can commence on January 31.

Thanks again for all your assistance.

Regards,

#### Christopher Martinez

StoneTurn Group, LLP 100 Congress Avenue, Suite 2000 Austin, TX 78738

(512) 469-5577 office (512) 422-2626 mobile cmartinez@stoneturn.com

Christopher Martinez.vcf

Campbell 30,007 45

# **Deposition Exhibit 34**

P's Exhibit OL

---Original Message--From: Davis, Brian [mailto:BDavis@choate.com]
Sent: Thursday, February 10, 2005 4:58 PM
To: D'Amore, Stephen
Cc: cmartinez@stoneturn.com
Subject: RE: Abbott/Hancock Audit Timing

### Steve.

John Hancock still needs a date certain by which Abbott will complete the production its books and records in response to Hancock's audit notification of April 12, 2004. So that there is no misunderstanding, by "date certain" I mean a definitive, honest-to-goodness date by which Abbott will complete its production once and for all. John Hancock asked for, and supposedly was provided with, Abbott's completion date last fall. Given that we are rapidly approaching the one year anniversary of John Hancock's audit request, your equivocal representation that Abbott now "is targeting the end of February" is not acceptable. Abbott's response to John Hancock's audit request already has been grossly and unreasonably delayed. A huge corporation like Abbott certainly has the resources necessary to complete the production process by now if it desired to do so. Please provide me with a final, definitive completion date by the end of this week.

On the topic of Abbott's production to date, I understood from your January 24, 2005 e-mail message to me that Abbott would produce an additional 24 boxes of documents by January 31, 2005. So far, only about one third of those boxes have been made available to John Hancock's auditors. Michelle Campbell has refused to provide any aformation to StoneTum representatives regarding the whereabouts or anticipated production date of the missing boxes. When will they be made available? Please let me know this week.

StoneTurn has received copies of the materials designated on January 31 and February 1. However, Abbott still has not produced copies of the following documents that were designated for copying by StoneTurn on January 20, 2005: (1) Box No. 4, Abbott ABT-724 Advisory Board Meeting 9/27-28/02, Day 1, Part A (narrative of discussions, 133 pgs.); (2) Box No. 4, Abbott ABT-724 Advisory Board Meeting 9/27-28/02, Day 1, Part B (narrative of discussions, 112 pgs.); and (3) Box No. 4, Abbott ABT-724 Advisory Board Meeting 9/27-28/02, Day 2 (narrative of discussions, 129 pgs.). Copies of these documents should have been delivered to StoneTurn over two weeks ago. Please make arrangements to have copies

CONFIDENTIAL

ABBT 0000175

Campbell 34

shipped to StoneTurn's offices immediately.

Lastly, Abbott's practice of redacting its books and records prior to their examination by John Hancock's auditors not only is unnecessarily delaying the production process, it also is unreasonably interfering with the ability of Stone Turn personnel to do their work. Attached to this e-mail, in PDF format, is an example of one five-page document that has been so heavily redacted by Abbott as to render the document meaningless. There are many others just like this one. StoneTurn previously has discussed this problem with Ms. Campbell and others at Abbott, who have offered no explanation or solution. Please make arrangements to have the original, unredacted versions of the documents produced to date by Abbott made available promptly for inspection by StoneTurn. In addition, I ask, yet again, that Abbott cease redacting its books and records as that practice is unnecessary in light of the confidentiality agreement in place between the parties, and contrary to the provisions of Section 2.5 of the March 13, 2001 Research Funding Agreement.

I look forward to your prompt response.

**Brian Davis** CHOATE, HALL & STEWART LLP Tele: 617-248-5056 E-mail: bad@choate.com

---Original Message----From: D'Amore, Stephen [mailto:SDamore@winston.com] Sent: Thursday, February 10, 2005 9:56 AM To: Davis, Brian Subject: Abbott/Hancock Audit Timing

### Brian

In response to your inquiries, Abbott is targeting the end of February to be complete or substantially complete with is production of materials in response to the audit request. I will let you know if that estimate changes, forward or back, before the end of February. As she has been doing, Michelle Campbell will let the StoneTurn people know when materials are ready for review. I trust StoneTurn received copies of the materials they designated during the week of January 31.

Stephen V. D'Amore Winston & Strawn LLP 35 West Wacker Drive Chicago, Illinois 60601 312.558.5934 312.558.5700 (fax)

The contents of this message are privileged and confidential. If this message is received in error, please destroy it without reading. This message should not be forwarded or distributed without the permission of the author.

2

CONFIDENTIAL

The contents of this message may be privileged and confidential. Therefore, if this message has been received in error, please delete it without reading it. Your receipt of this message is not intended to waive any applicable privilege. Please do not disseminate this message without the permission of the author.

Confidentiality Statement:

This message is transmitted to you by the law firm of Choate, Hall & Stewart LLP. The substance of this message, along with any attachments, may be confidential and legally privileged. If you are not a designated recipient of this message, please destroy it and notify the sender of the error by capit or the capital 1,800,500,2427 reply e-mail or by calling 1-800-520-2427.

For more information about Choate, Hall & Stewart LLP, please visit us at www.choate.com.

Page 2.jpg



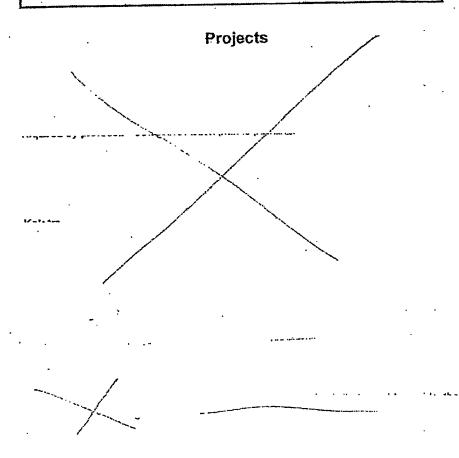
Page 1.jpg

Page 4.jpg

CONFIDENTIAL

REDACTED

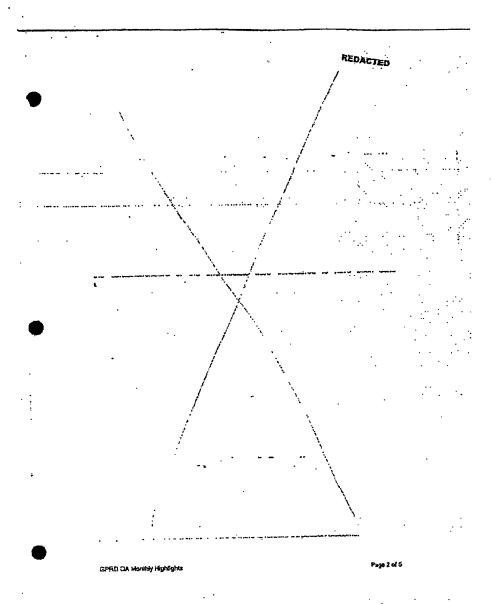
## GPRD Quality Assurance Monthly Highlights December 2003



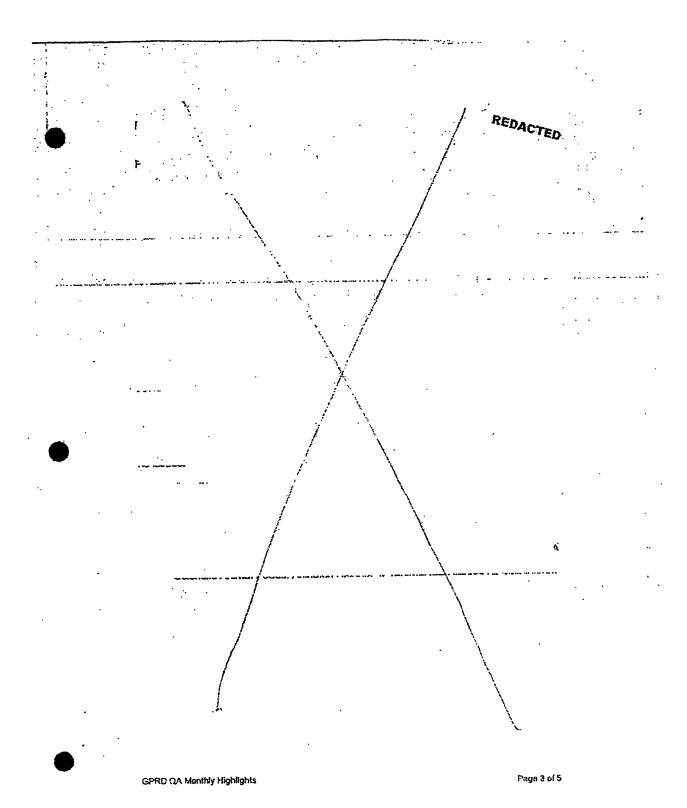
GPRD QA Monthly Highlights

Page 1 of 5

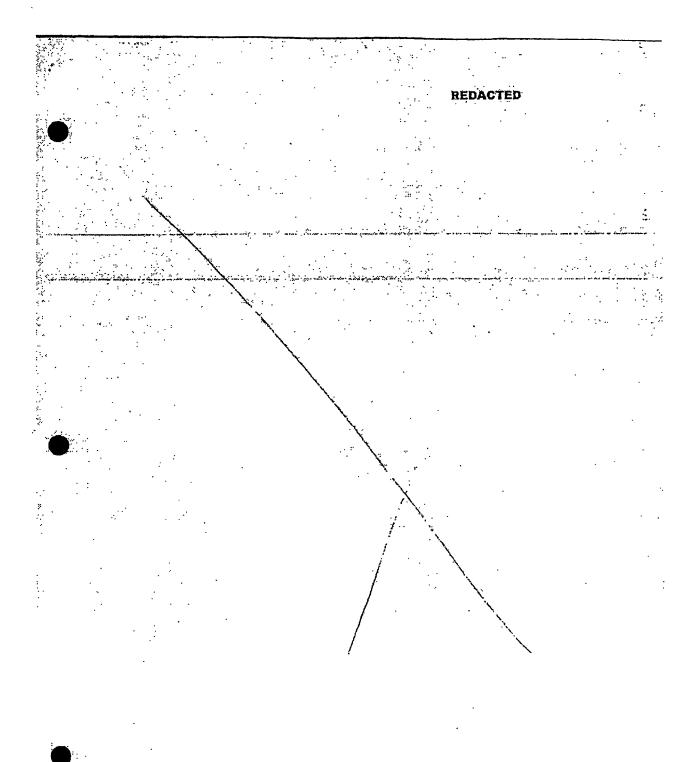
CONFIDENTIAL



CONFIDENTIAL



CONFIDENTIAL



GPRO QA Monthly Highlights

Page 4 of 5

CONFIDENTIAL



GPRD QA Monthly Highlights

Page 5 of 5

CONFIDENTIAL

ABBT 0000181A

# **Deposition Exhibit 36**

P's Exhibit 48

Page 1 of 2

### Mark Hair

From:

Mark Hair

Sent:

Thursday, March 10, 2005 12:21 PM

To:

Michelle L Campbell

Cc:

Chris Martinez

Subject:

JH - Abbott Audit Documentation

Attachments: Schedule A Status 3-10-05.xls

### Michelle,

It was good to meet you briefly yesterday in Mundelein. As I mentioned yesterday, we have some observations and questions related to the documents provided for the audit.

This week, a total of 17 new boxes were provided for review. We flagged documents to be copied, gave requests to Carey Crimmins, and several boxes have already been sent out for copying. When should we plan to receive the copied documents? Please continue to send copies to my attention at the address below.

Also, we noted some financial documents/spreadsheets that appeared to provide cost details for one of the Program Compounds, ABT-627. The formatting of the documents caused various costs to be printed on separate pages from the cost descriptions, making the financial reports unusable. We discussed this issue with Carey and flagged this report as well as other documents for further follow up. We would like electronic copies of these documents or have documents printed in a usable format. Additionally, the above mentioned spreadsheet appears to be only related to program costs incurred for ABT-627 during 2004. Are similar reports available for the other Program Compounds and other years (2000 – 2004)? If so, when will these documents be made available for review?

We also noted that there are no emails included in the boxes related to the Program Compounds. It is our understanding that requests were made for emails to be available for review. Have emails been provided in the available documents? If so, which boxes contain these emails? If they have not yet been produced, when will they be available for review?

As we left the Mundelein facility today, Carey said that there was one additional set of documents (less than one box) that was not available at the time of our review, but that the entire set of documents would be copied and sent to us. Except for this one set of documents, Carey was not aware of any additional documents that were going to be produced for the audit. I wanted to confirm this with you as well. Have all documents been made available for the audit? Are you aware of any additional documents that have not yet been provided to us? If so, when will additional documents be available for review?

Attached is a spreadsheet summarizing John Hancock's requests for information/documentation as included in Schedule A of the April 12, 2004 letter from Steven Blewitt. Are all documents related to these requests included in the documents currently available for review? With respect to each of the requested items from Schedule A, please respond to the following:

- (i) Whether all requested information/documents have been produced for the Audit
- (ii) The titles and descriptions of the responsive documents
- (iii) The location of the documents, including site and box number

Thank you for your assistance, and I look forward to hearing from you.

Campbell 36

CONFIDENTIAL S0017

Page 2 of 2

Mark Hair StoneTurn Group, LLP

Office: 925-974-3376
Fax: 925-974-3338
Mobile: 203-300-3692
mhair@stoneturn.com
www.stoneturn.com

2121 N. California Blvd., Suite 290 Walnut Creek, CA 94596

Location of Information [Site & Box #]

> of Responsive Documents Titles and Descriptions

All Items Have Been Produced for the Audit

All records and documents indicating expenditures made by Abbott related to any compound that is now or ever was a Program Compound, including the following: Requests\*

- Abbott's standard policies and procedures related to accounting for
- Abbott's chart of accounts as relevant to accounting for project/program project/program related expenditures;
- Summary of costs/expenditures incurred by Program Compound by year delineating expenditures by nature (e.g., direct costs incurred by Abbott, related expenditures;
  - Accounting framework for compiling the expenditures presented (i.e., whether cost assembled on an accrual or cash basis of accounting); subcontractor costs, allocated indirect costs, etc.);
    - expensed under General Accepted Accounting Procedures ("GAAP"; identification of whether expenditures presented were capitalized or
- Summary of the timing of expenditures for each Program Compound within each year presented;
- Contracts or other governing documents and information related to all Research Program activities performed by Subcontractors;

တ်

- Reconciliations of annual expenditures by Program Compound to the Ë
- audited financial statements of Abbott;
- Calculations, algorithms, and basis for all allocations included in the total expenditures by Program Compound by year, Abbott standard policies and procedures related to allocation of indirect
- Expenditures/Costs summaries and/or reports prepared in the normal course of managing the development of each Program Compound; and
  - Underlying supporting records (e.g., timesheets, payroll records, purchase orders, invoices, etc.) for all expenditures made related to each Program Compound
- All records and documents discussing or evidencing the implementation and conduct of the Research Program, including but not limited to: ٨i
- Reports/Updates/Summaries prepared by Abbott in the normal course of managing the development of the Program Compounds; гó نم
  - during the normal course of developing an experimental pharmaceutical Listing of all reports/updates/summaries typically prepared by Abbott :punodwoo
- Minutes/Summarles/Notes from all management meetings in which any of the Program Compounds where reviewed or approved for further development funding; ن
  - Analysis and documentation supporting all forward looking projections of expenditures to be incurred for each Program Compound by year; Ą,
- methods/approaches/procedures for conducting a research program for an Abbott policies and guidance as to the appropriate and/or required

per Schedule A of April 12, 2004 letter from John Hancock to Abbott

Page 1

nent with Abbott	
ohn Hancock Audit of Research Funding Agreement with Abbott	tatus of Information and Document Requests

	Titles and Descriptions	of Responsive Documents
All Items Have Been	Produced for the Audit	[Y/N]
		[Y/N] of Responsive Documents
		*S1
		Regues

Location of information

Abbott's Internal approval framework for determining whether or not to continue to fund and develop an experimental pharmaceutical compound inciuding all relevant thresholds for approval along the compound

Minutes/Summaries/Notes from all Abbott meetings regarding continued funding of product development for any Program Compounds.

development process; and

All records and documents concerning Abbott's obligations under § 4.3 of the Agreement, including but not limited to: Ġ

લ

Records identifying any and all Repiacement Compounds; Records identifying any and all Falled Early Stage Program Compounds; Records identifying any and all Ceased Compounds; க் ம்

ن

d. All documents pertaining to Abbott's consideration or selection of any

considered to be "back up" compounds for the compounds that constituted the Program Compounds (I) on the effective date of the Agreement, and compound to replace any Falled Early Stage program Compound; Records identifying any and all compounds that Abbott held out as or

(ii) as of the end of each calendar year 2001 through 2003; and All documents pertaining to the actual or attempted out-licenship or divestiture of any Ceased Compound. All records and documents concerning the status of each Program Compound as of March 13, 2001 and currently, including but not limited to: 4.

development of each compound that originally constituted a Program Reports/Summarles/Meeting Minutes which indicate the stage of Compound during the first calendar quarter of 2001;

Records describing the various stages into which Abbott generally categorizes the pre-clinical and clinical development of experimental pharmaceutical compounds;

Records indicating when each Program Compound reached each stage of pre-clinical or clinical development into which Abbott generally categorizes the pre-clinical and clinical development of experimental pharmaceutical compounds;

Management Reports and/or other documents prepared in the normal course of business which indicate future prospects and development expectations for each Program Compound. each Program Compound; and

Reports/Summaries/Meeting Minutes which evidence the current status of

per Schedule A of April 12, 2004 letter from John Hancock to Abbott

Page 2

### **Deposition Exhibit 37**

P's Exhibit 49



03/22/2005 04:43 PM

To mhair@stoneturn.com

O

bcc

Subject Hancock Audit

Hi Mark -

I am responding to your March 10, 2005 e-mail regarding the audit documents. You should have received today the final box of copies of documents from among those designated during the week of March 7, 2005. You should receive by the end of this week additional documents, less than one box, that were not available for review before your team left on Thursday, March 10.

Regarding the spreadsheet for ABT-627 mentioned in your e-mail, I will also try to send either an electronic version of the spreadsheet or a more easily readable print out of the spreadsheet as soon as possible.

Finally, regarding your remaining questions and request for identification of the specific documents that respond to each category of Hancock's audit requests, Abbott has fulfilled its obligation to comply with the audit provision of the contract, subject to the production of the remaining number of documents mentioned above

Kind Regards,

Michelle

Michelle L. Campbell Litigation Paralegal Abbott Laboratories Dept. 324 Bidg. AP6D 100 Abbott Park Road Abbott Park, Illinois 60064 Phone: 847-937-1518 Fax: 847-938-6235

This communication may contain information that is legally privileged, confidential or exempt from disclosure. If you are not the intended recipient, please note that any dissemination, distribution, use or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by return e-mail, and delete it from his or her computer.

Campbell 37